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IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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QUESTIONS PRESENTED FOR REVIEW

1. Is the "reasonable anticipation" standard, rejected by this Court in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982) as a "watered down and improper standard" under Section 32 of the Lanham Act, 15 U.S.C. §1114 for restraining sale of a generic drug in the accustomed appearance for the drug, the proper standard for restraining the same conduct under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a)?

2. Does the decision below improperly evade the Lanham Act legal standards for "functionality" and "secondary meaning", affirmed by this Court in *Inwood, supra*, by applying New Jersey state law to prohibit interstate commerce throughout the United States in a generic drug product lawfully manufactured in another state and lawfully approved in its publicly accustomed appearance by the United States Food and Drug Administration, thereby interfering with the drug substitution laws of the other states?

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

OPINIONS BELOW

The opinion of the District Court for the District of New Jersey is reported at 215 U.S.P.Q. 769 (1982). It is reprinted in the Appendix at App. 8-50. The unreported preliminary injunction entered by the District Court on October 4, 1982 is reprinted in the Appendix at App. 5-7. The unreported decision of the Third Circuit Court of Appeals is reprinted in the Appendix at App. 1-4. The unreported orders of the District Court converting the preliminary injunction hearing to a final trial on the merits and entering a permanent injunction are reprinted in the Appendix at App. 51-55.

JURISDICTION

A writ of certiorari is sought to review the judgment of the United States Court of Appeals for the Third Circuit dated and entered October 14, 1983. The jurisdiction of this Court is invoked under 28 U.S.C. §§1254(1) and 2101(c).

STATUTES INVOLVED

The federal statutory provision involved is Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a). The state statutory provisions involved are New Jersey Statutes Annotated, Sections 56:4-1 and 56:8-2. These provisions are set forth in full in the Appendix at App. 56-57.

STATEMENT OF THE CASE

This is an action brought by Ciba-Geigy Corporation ("Ciba") against Bolar Pharmaceutical Co., Inc. ("Bolar"), Petitioner herein, under Sections 32 and 43(a) of the Lanham Act, and New Jersey state law, to restrain Bolar's manufacture in New York of a generic prescription drug in the same color capsules used by Ciba for the same drug. Full evidentiary hearings were held in April, May and June, 1982. Also in June, 1982, this Court unani-

mously decided *Inwood Laboratories, Inc. et al. v. Ives Laboratories, Inc.*, 456 U.S. 844 in favor of generic drug manufacture in publicly accustomed capsule colors.

Nevertheless, by opinion dated August 11, 1982, the trial court applied the "reasonable anticipation" standard specifically rejected by this Court in *Inwood*, to find Bolar guilty of "passing off" an "unprivileged imitation" under the Lanham Act and New Jersey state law, despite the fact that there was no illegal substitution or "passing off" of the Bolar product for the Ciba product. (App. 46). The trial court also specifically declined to follow the legal standards for "functionality" and "secondary meaning" of drug appearance affirmed by this Court in *Inwood*.[1]

On appeal, the Third Circuit summarily affirmed the trial court (App. 1-4). The Third Circuit recognized the conflict with this Court's *Inwood* decision, but held it was not required to address the issue of conflict with *Inwood* under the Lanham Act because the lower court's injunction could be based solely on New Jersey law:

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[1] The trial court acknowledged that use of accustomed colors "will facilitate generic substitution" (App. 18, 47) but "predicate[d]" its "rule of law upon an assumption that some pharmacists do and may illegally substitute generic drugs" (App. 32) and asserted that its "indictment could logically extend to any generic manufacturer who produced a look-alike drug" (App. 30). This was despite the rejection by this Court in *Inwood* of a rule of law based on the "assumption that a pharmacist . . . will be unable to resist the temptation to profit from illegal activity" (456 U.S. 844 at 856, footnote 17). In making this assumption, the trial court relied on a number of indictments of pharmacists in New York City for welfare fraud. The drugs involved were not the products in suit here; they included generic drugs available in different colors, so that the indictments are not probative of the drug appearance issue (DX 12A). Reliance on such indictments was criticized by this Court in *Inwood* (*Id.* at 857).

> However, we need not address this issue because the district court's conclusions regarding the New Jersey state law claims of "passing off" and "unprivileged imitation" are mandated by *SK&F* and provide a sufficient independent basis for affirming the district court's grant of preliminary injunctive relief. (App. 4).

This was despite its earlier holding in *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1065 (1980) that the legal standards for New Jersey state law were the same as those for the Lanham Act.

The Third Circuit reliance on New Jersey state law is a transparent effort to evade *Inwood*. Bolar is a New York corporation which manufactured its generic product in New York and intentionally avoided selling its product into New Jersey. New Jersey has no interest in or subject matter jurisdiction over Bolar's interstate generic drug business outside of New Jersey.[2]

1. History of the Drug Products in Suit

Respondent Ciba is the U.S. arm of a major Swiss drug conglomerate, Ciba-Geigy A.G. Ciba has a prominent market position in antihypertensive (blood-pressure reducing) drugs. As a result of antitrust action brought by the Justice Department against Ciba, its patents covering the product in suit were dedicated to the public in 1981. *U.S. v. Ciba-Geigy Corporation*, 1976-1 Trade Cases ¶60,908 (D. N.J., 1980).

In August of 1976, Ciba's competitor Pfizer began to market Minipress (Prasosin), a new antihypertensive drug.

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[2] Ciba asserted jurisdiction under 15 U.S.C. §1121; 28 U.S.C. §§1331, 1338, and the doctrine of pendent jurisdiction. The lower courts have declined to consider Bolar's objection to subject matter jurisdiction under New Jersey state law.

The two principal dosages of Minipress were in pink/white and blue/white capsules [R. 60-61, 800-802, 1045, 1199; DX 57, 40, 13A, 13B, 1, 2]. Ciba was simultaneously attempting to launch a new antihypertensive named "Apresazide" containing two different chemical ingredients, in order to maintain its market share.

At the time Pfizer introduced Minipress, Ciba discovered that its first production batches of Apresazide were decomposed and adulterated by an unknown brown chemical reaction product. Rather than fall further behind Pfizer by developing a pure drug, Ciba deliberately shipped the decomposed and adulterated Apresazide into commerce in October, 1976 without first advising or seeking approval from the Food and Drug Administration for the contaminant as required by law, 21 U.S.C. §§334, 351 [R. 1381-1386; DX 81, 83, 84],[3] see *United States v. Generix Drug Corp.*, ... U.S. ..... (March 22, 1983).

Ciba's introduction of its adulterated Apresazide was two months after Minipress came on the market. The pink/white and blue/white capsule colors of the two principal dosage forms of Apresazide are identical to the corresponding colors of the Minipress capsules [PX 2, 3, DX 1, 2, 13A, 13B, 41; R. 800-802, 1047].

At the time Ciba introduced Apresazide, the prestigious National High Blood Pressure Education Program Task Force had divided proper hypertension therapy into a sequence of four drug treatment steps, steps 1-4. Accord-

[3] Record references are to the numbered pages of the Record on Appeal, and include documentary exhibits. Physical exhibits are referred to by trial exhibit number. Petitioner has requested the entire record be transmitted to this Court.

ing to the Task Force recommendations, drugs for step 2 should not be used unless step 1 treatment would not work. Because of its dangerous side effects, the Task Force classified Apresazide as a "step 3" drug, which should not be used unless "first step" and "second step" drugs were ineffective [R. 1289, 1294]. To overcome the Task Force recommendations, Ciba decided to falsely promote Apresazide as "second step" therapy because Ciba did not want Apresazide "to end up as a third step in the therapy sequence . . . because most patients just don't get to a step 3 situation" [R. 1422; DX 102]. Ciba instructed its salesmen how to respond "in the unlikely event" they were questioned about their "second step" promotion [R. 166-167, 1289, 1419, 1442]. Ciba also deliberately violated the generic name labelling requirements of the Food, Drug and Cosmetic laws by not selecting and prominently printing a useful generic name on its promotional materials as required by the Food and Drug laws.[4]

In 1976, Bolar decided to market a generic version of Apresazide and chose to use standardized capsule appearance for reasons of public safety [R. 610-615]. Bolar's application to the Food and Drug Administration for approval of its generic product in the pink/white and blue/white capsules by which the public recognized and identified the drug was approved by the FDA on March 4, 1982. In contrast to

[4] This illegal conduct is remarkable because it was Ciba's own deceptive advertising of Singoserp, another of its antihypertensive drugs, and the failure of its advertising agency to display generic drug names, which resulted in 1962 Amendments to the Food and Drug laws, 21 U.S.C. §§ 352(e), (n) prohibiting such deceptive drug advertising and requiring selection and prominent display of a generic name [R. 952, 965].

the adulterated drug marketed by Ciba, Bolar's generic drug is of the highest quality [R. 432-33]. Before being restrained by the trial court, Bolar marketed its generic product to government agencies, wholesalers and distributors, in distinctive containers with a prominent yellow label cautioning pharmacists to substitute only where permitted by law and only after informing the patient of the substitution [PX 16-17]. Bolar's generic capsules themselves each had Bolar's logo and its National Drug Control Identification Number prominently imprinted on them twice so that Bolar could be readily identified as the source of its product [PX 16-17].

2. The Evidentiary Proceedings

In support of its case, Ciba called Henry Kirsch, its sales director for Apresazide, who admitted that all of Ciba's promotion was directed to physicians and pharmacists, and not to patients [R. 14-19, 93]. Kirsch was unable to distinguish Apresazide capsules from the earlier Minipress capsules and from other earlier capsules also identical in appearance [R. 347-348]. Kirsch admitted that patients associate the capsule colors with the medication itself and do not associate the capsule colors with Ciba [R. 81, 87]. Kirsch also admitted that the names of the ingredients of Apresazide were too cumbersome to use as a generic name, that Apresazide is the common descriptive name for Ciba's product, and that physicians commonly refer to the product in suit as Apresazide [R. 73-77].

Ciba's other employee-witness was Dr. Audrey Kriegman, a recent medical school graduate who has never been in private practice [R. 120, 129, 1795]. She admitted that the name Apresazide served as the common name of the

drug itself, and that patients do not associate the capsule colors with Ciba [R. 136, 143, 147].

Bolar called two expert witnesses, Dr. James O'Donnell, a pharmacist, and Dr. Herbert Silberner, a physician. Dr. O'Donnell is Assistant Director of Pharmacy at Rush Medical Institute, a prominent Chicago hospital center, and a member of the Generic Drug Technical Advisory Council of the State of Illinois which is responsible for approval of all generic drugs in the state [R. 312-316]. Dr. Silberner is a New Jersey physician who has specialized in internal medicine since 1948, and who writes a majority of his prescriptions for generic drugs [R. 507].

Both Dr. O'Donnell and Dr. Silberner testified that capsule color is functional in many ways. To the patient, capsule color identifies the medication itself, and also serves to distinguish one medication from another when two or more dosage forms are intermingled [R. 351, 369, 372]. Capsule color is especially helpful to elderly patients in identifying medication and identifying the purpose of the medication and should be the same regardless of manufacturer [R. 510-513]. Capsule color enables a patient to detect a dispensing error by a pharmacist; Dr. O'Donnell testified from personal experience of instances where a prescription that he had erroneously filled with the wrong medication was returned by a patient who noticed the different color of the medication [R. 376].

Dr. O'Donnell and Dr. Silberner also testified that it is common for patients to resist taking a generic equivalent if the generic drug is a different color because the patient thinks it is an entirely different drug [R. 509-514, 581-585].

Dr. O'Donnell serves as a volunteer at the Chicago Poison Control Center, which gives information to health care specialists about the identity of drugs which have been accidentally or intentionally ingested. Here, too, the color of the drug functions as a means of identifying unknown drugs [R. 373-374]. For this reason and others unrelated to the source of the drug, he testified that when in charge of purchasing drugs for major Chicago hospitals he would pay a significant premium for a generic drug having the publicly accustomed color than for one having a different color [R. 364].

Dr. O'Donnell also confirmed the testimony of Mr. Kirsch and Dr. Kriegman that the term "Apresazide" is the common descriptive name of the drug itself, because Ciba did not select and properly promote any other generic name for Apresazide. A tongue twisting list of its ingredients—"Hydralazine Hydrochloride and Hydrochlorothiazide"—is simply too cumbersome for use, and hence everyone must necessarily use Apresazide as the name of the drug itself [R. 353-361].

Dr. Silberner testified that, to the patient, color functions to identify the medicine itself. When Dr. Silberner prescribes a medication, he offers the patient a generic drug. Even though his patients know that he has prescribed a generic drug (and thus are not confused as to source), they will call both the pharmacist and physician to check whether the correct medicine has been dispensed if it has an unaccustomed appearance [R. 509-514]. None of Dr. O'Donnell's or Dr. Silberner's testimony as to the functionality and meaning of drug color was controverted by Ciba in any way.

REASONS FOR GRANTING THE WRIT

A. The Decision Below Conflicts With This Court's Decision In *Inwood* By Applying The Watered Down And Incorrect Reasonable Anticipation Standard To Prohibit Manufacture And Sale Of A Generic Drug Product In The Accustomed Appearance For The Drug

The decision below is in conflict with the principles established in this Court's decision in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982) and with the decision of the Second Circuit in that case following remand, *Ives Laboratories, Inc. v. Darby Drug Co.*, No. 80-7314 (July 7, 1982) (App. 58-60), rejecting the "reasonable anticipation" standard for prohibiting generic drug manufacture in the accustomed drug appearance. Based on their anti-generic drug position, the New Jersey federal courts have become a haven for drug companies seeking protection from generic competition after their patents expire. Bolar and other generic drug companies are now repeatedly being sued in New Jersey for sale of generic drugs in their accustomed color. By evading the rationale of the Court's *Inwood* decision, the New Jersey District Court has effectively established a national policy against manufacture and sale of a generic drug in the only appearance by which the public recognizes the drug.

The undisputed facts here are more compelling than in *Inwood*. Although over a million capsules of Bolar's generic product were sold before Bolar was restrained by the lower courts, there was no evidence of any illegal substitution or "passing off" of Bolar's product for Ciba's product. Nevertheless, the lower courts found that Bolar "passed off" its generic drug by applying the "reason-

able anticipation" test rejected by this Court and the Second Circuit in *Inwood*.

Justice White expressed his concerns in *Inwood* that a generic drug manufacturer should not be held vicariously liable merely because it could "reasonably anticipate" some infringement by its customers:

> The mere fact that a generic drug company can anticipate that some illegal substitution will occur to some unspecified extent, and by some unknown pharmacists, should not by itself be a predicate for contributory liability. . . .
>
> Diluting the requirement for establishing a prima facie case of contributory infringement is particularly unjustified in the generic drugs field. Preventing the use of generic drugs in the same color to which customers had become accustomed in their prior use of the brand name product interferes with the important state policy, expressed in New York and 47 other states, of promoting the substitution of generic formulations. (456 U.S. 861, 862) (Justice Marshall concurring)

The majority opinion in *Inwood* addressed this issue by specifically rejecting the "reasonable anticipation" standard:

> JUSTICE WHITE'S concern is based on a comment by the Court of Appeals that the generic manufacturers 'could reasonably anticipate' illegal substitution of their drugs. 638 F.2d at 543. If the Court of Appeals had relied on that statement to define the controlling legal standard, the court indeed would have applied a 'watered down' and incorrect standard. (456 U.S. 854, note 13)

Because the Second Circuit had based its decision only on §32 of the Lanham Act, this Court could not specifically reject the "reasonable anticipation" standard under

§43(a). On remand the Second Circuit affirmed the judgment in favor of the right to manufacture the drug in its accustomed capsule colors under §43(a) without applying the "reasonable anticipation" standard (App. 58-60). There is no suggestion in *Inwood* that the "reasonable anticipation" standard rejected by this Court under §32 of the Lanham Act is a proper standard under Section 43 of the Act. There is no public policy reason to apply one standard for vicarious liability for "passing off" under §32, and a lesser standard for "passing off" under §43(a).

Nor can *Inwood*'s rejection of the "reasonable anticipation" standard be avoided by the lower courts' presumption that Bolar "intended" to "permit" or "facilitate" illegal substitution by unknown retail pharmacists because it manufactured a product in the only appearance by which it is recognized by the consuming public. That is merely another way of stating that Bolar could "reasonably anticipate" passing off. As pointed out by Justice White in his concurring *Inwood* opinion:

> A functional characteristic is "an important ingredient in the commercial success of the product," 601 F.2d, at 643, and, after expiration of a patent, it is no more the property of the originator than the product itself. It makes no more sense to base contributory infringement upon the copying of functional colors than on the petitioners' decision to use the same formulation of the drug, or even to market the generic substitute in the first p ce. To be sure, the very existence of generic drugs "facilitates" illegal substitution. But Ives no longer has a patent for cyclandelate, "and the defendants have a right to reproduce it as nearly as they can." *Saxlehner v. Wagner*, 216 U.S. 375, 380 (1910) (Holmes, J.). Reproduction of a functional attribute is legitimate competitive activity. [*Id.* at 863]

There is no evidence in the record of any "intent" by petitioner to condone or allow any such wrongdoing; as

the district court's opinion makes clear, petitioner's asserted "intent" in this regard is nothing more than the court's application of the "reasonable anticipation" standard rejected by this Court in *Inwood*. This Court held in *Inwood* that generic manufacturers are free to adopt the accustomed drug appearance, despite the "reasonable anticipation" of wrongdoing by others, so long as they do not encourage or condone the wrongdoing. What the lower courts have done here is to ignore the substantive underpinning of *Inwood* in an attempt to distinguish *Inwood* as a "narrow" case involving only the scope of appellate review.

We believe that Section 43(a) does not constrain the freedom of a generic drug manufacturer to adopt the accustomed appearance for a drug any more than Section 32 does, and that this Court would not have upheld that freedom under one section of the Lanham Act only to watch it perish under another. But if the *Inwood* holding is to perish, surely it should do so only after plenary review of the matter by this Court. The decisions below do not address the issue, let alone subject it to the scrutiny that it deserves.

The lower court's finding that Bolar has "passed off" its generic product is based on the faulty premise that Ciba is entitled to the market demand for the drug product itself, and that because Ciba first encouraged doctors to prescribe it, it is unfair competition for Bolar to produce and sell a generic drug at "much lower cost" (App. 9).

This Court has struck down every attempt to use the trademark laws to prevent competition and extend a patent monopoly. *Scott v. Marcalus*, 326 U.S. 249 (1945); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120-122

(1938); *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896). In *Scott v. Marcalus*, the Court held the goodwill of a product (i.e., the demand for a product in its accustomed form) was public property:

> By the force of the patent laws not only is the invention of a patent dedicated to the public upon its expiration, but the public thereby becomes entitled to share in the goodwill which the patentee has built up in the patented article or product through the enjoyment of his patent monopoly [p. 256].

This Court has never permitted monopolists to appropriate the demand and goodwill associated with the product itself as it was known to the public during the term of the monopoly. As the Court stated in its landmark *Kellogg Co. v. National Biscuit Co.* decision:

> Since during the life of the patents "Shredded Wheat" was the general designation of the patented product, there are passed to the public upon the expiration of the patent, not only the right to make the article as it was made during the patent period, but also the right to apply thereto the name by which it had become known.
>
> * * *
>
> Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights *in a form in which the public has become accustomed to see the article* and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind. (emphasis supplied)
>
> * * *
>
> Kellogg Company is undoubtedly sharing in the goodwill of the article known as "Shredded Wheat"; and thus is sharing in a market which was created by the skill and judgment of the plaintiff's predecessor and has been widely extended by vast expend-

> itures in advertising persistently made. But that is not unfair. Sharing in the goodwill of an article unprotected by patent or trade-mark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested. [305 U.S. 111, 118-122]

The so-called "patent clauses" of the Lanham Act, 15 U.S.C. §§1064(c), 1065(4), were passed by Congress specifically to codify the *Scott*, *Kellogg*, and *Singer* cases, to subordinate the trademark law to patent law, and to protect small drug companies such as Bolar from assertions of trademark law as a legal device to perpetuate a monopoly. See Abraham S. Greenberg, *"Patent" Clauses of the Lanham Act*, 38 Trademark Reporter, pp. 3-47, 19 (1948).

This Court should strike down the use of the "reasonable anticipation" standard to prevent competition and perpetuate drug monopolies.

B. The Decision Below Conflicts With The Decisions Of This Court And The Second Circuit In *Inwood* As To The Standards For "Functionality" Of Drug Color

In *Inwood*, this Court reaffirmed the general test for functionality of a product feature.

> In general terms, a product feature is functional if it is essential to the use or purpose of the article or it affects the cost or quality of the article. See *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 238 (1964); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 122 (1938) [456 U.S. 844, 850]

The evidence is uncontradicted that purchasers such as hospitals (where there is no possibility whatsoever of illegal substitution) will pay a substantial premium to have the generic drug in its accustomed appearance, *irrespective of source*, purely because of the desire to have

the generic drug in the only form by which it has been recognized and identified by patients and to minimize staff training and dispensing error[5] [R. 364-365]. This price premium is substantial, approximating Ciba's entire cost of manufacture of its product [R. 1455; DX 111]. Moreover, the District Court specifically found that the accustomed appearance of the drug makes it "more saleable, because it makes it easier for both the doctor and the pharmacist to substitute the generic drug" (App. 9). The District Court also found that patients will "accept the generic drug more readily" if it has the accustomed appearance by which it is identified and "may resist such substitution, if it does not"[6] [App. 9]. It is also undisputed that Bolar's customers, which include Government agencies, wholesalers and distributors, prefer the product in the accustomed form [R. 364, 218-219, 1589].

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[5] Other circuits in addition to the Second Circuit recognize as "functional" any feature which has value, apart from source identification, which is important to the commercial success of the product. *West Point Manufacturing Co. v. Detroit Stamping Co.*, 222 F.2d 581 (6th Cir. 1955); *Pagliero v. Wallace China Co.*, 198 F.2d 339 (9th Cir. 1952). See also *Vibrant Sales, Inc. v. New Body Boutique, Inc.*, 652 F.2d 299 (2nd Cir. 1981); *Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569 (2nd Cir. 1959), *cert. denied*, 362 U.S. 919 (1960); *American Safety Table Company v. Schreiber*, 269 F.2d 255 (2d Cir. 1959); *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, 64 F.Supp. 980 (D. Mass. 1946), *aff'd* 162 F.2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947).

[6] The District Court Opinion was largely copied verbatim from Ciba's post-trial submissions, and is thus "loaded down with argumentative overdetailed partisan matter . . . of doubtful validity or even wholly without support in the record" *Roberts v. Ross*, 344 F.2d 747, 751-752 (3rd Cir. 1965). However, these findings as to increased "saleability" were written by the Court and, presumably, more accurately reveal the Court's reasoning.

As pointed out in *Famolare, Inc. v. Melville Corp.*, 472 F. Supp. 738 (D. Hawaii, 1979), *aff'd* 652 F.2d 62 (9th Cir. 1981):

> A feature which gives the consumer a substantial reason for purchasing the product, as opposed merely to distinguishing it from other products, is functional.
>
> * * *
>
> Free competition would be impeded if a manufacturer could gain a perpetual monopoly on the reproduction of a feature which contributes directly to the sale of the underlying product. [*Id.* at 743]

The record and the Court's own findings confirm a commercial cost premium, "saleability" and preference for the accustomed drug appearance, *irrespective of source*, because it is the accustomed and only known identification of the drug itself. The accustomed appearance "affects the cost of the drug" and is accordingly functional under the general *Inwood* test. To give a former patent monopolist an undeserved price advantage approximating the cost of manufacture is contrary to the purpose and policies of the trademark, patent and antitrust laws.

In addition to the general test for functionality, this Court affirmed in *Inwood* specific tests of functionality for drug product appearance established by the trial court:

> . . . that the blue and blue-red colors were functional to patients as well as to doctors and hospitals: many elderly patients associate color with therapeutic effect: some patients co-mingle medications in a container and rely on color to differentiate one from another: colors are of some, if limited, help in identifying drugs in emergency situations: and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs. [456 U.S. 844 at 823]

The record in this case clearly establishes without contradiction each of these elements of functionality, and more. Capsule colors of Apresazide are functional to patients as well as to doctors, pharmacists and hospitals [R. 81-82, 351, 372, 374-376, 419-420, 424-425, 510-512, 830-839, 1829, 1832;—DX 25, DX 26]. Patients associate color with therapeutic effect and use color to identify the medication itself and its purpose [R. 351-369, 372, 376, 510-511]. Patients co-mingle different medications in a container and rely on color to distinguish one from another [R. 423-425, 510-512; DX 28, DX 29]. Drug appearance functions to distinguish different dosages of a medication, serves as a means for drug identification in emergency situations, facilitates doctor-patient communication and helps avoid confusion in drug dispensing [R. 374-376]. Functionality of drug appearance prevents prescription error and patient harm or death [R. 375-376].

The lower courts specifically rejected these tests and refused to consider the record evidence which fully supports functionality under the tests [R. 697]. For the *Inwood* tests that color may be associated with therapeutic effect and used by patients to distinguish co-mingled medication, the District Court presumed that "constancy" of accustomed drug appearance "will *permit* the patient to identify it with a single source" [App. 38]. This, despite the lack of any advertising to patients.

The District Court rejected the *Inwood* tests "that uniform color *helps* to avoid confusion on the part of those responsible for dispensing drugs", and that "colors are *some, if limited help* in identifying drugs in emergency situations" [456 U.S. 844 at 853]. It substituted its own presumption of law that a drug is functional if a "physician or a pharmacist would prescribe a drug based upon its appearance *only*" and that it must be a dangerous drug

"likely to engender . . . emergency room visits" or "overdose" [App. 37]. This was despite the fact that Apresazide is sufficiently more dangerous than the drug involved in *Inwood*, that the FDA requires a "box warning" for Apresazide [R. 1916-1917; DX 12A—1982 Physicians' Desk Reference]. The lower courts also ignored Dr. O'Donnell's testimony about dangerous prescription errors which are and have been detected by drug appearance alone [R. 375-376]. They also ignored the position of the 55,000 member American Pharmaceutical Association, which is that if standardized drug appearance is prohibited, "the possibility of drug overdose is increased . . . [and] the problem of drug identification in emergency situations, such as accidental poisoning is exacerbated" [R. 831-32].

The apparent basis for the District Court's refusal to adopt the standards for functionality approved by this Court in *Inwood* is its conclusion that color is not functional because patients who identify a drug by its color may be persuaded by doctors and pharmacists that the same drug may have a different color.[7] The District Court reasoned that Bolar therefore must use different colors to avoid any possibility of confusion (App. 22). The District Court's reasoning is in conflict with the holding of this Court in *Kellogg Co. v. National Biscuit* that a competitor is not required to adopt a product appearance different from the accustomed form:

---

[7] The Court found that when "a patient already on a brand name product is then dispensed a different-looking generic equivalent . . . the patient will usually call his physician or pharmacist to inquire whether the correct medication has been dispensed." (R. 698). Because the physician tells the patient a generic drug is being dispensed (and indeed, the patient can see this on the prescription itself), this finding *is conclusive proof that accustomed drug appearance identifies the drug product*, not source, defeating the

(Footnote continued on following page)

> It is urged that all possibility of deception or confusion would be removed if Kellogg Company should refrain from using the name "Shredded Wheat" and adopt some form other than that pillow-shape. But the name and form are integral parts of the goodwill of the article. To share fully in the goodwill, it must use the name and the pillow-shape. And in the goodwill Kellogg Company is as free to share as the plaintiff. Compare *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526, 528, 530.

Id. at 121. To share fully in the goodwill of the drug product itself, generic drug companies must be permitted to use the publicly accustomed appearance of the drug.

C. The Decision Below Conflicts With The Decisions Of This Court And The Second Circuit In *Inwood* As To The Standards For Establishing "Secondary Meaning" Of Drug Color

The lower courts failed to follow the long established test for secondary meaning reaffirmed by this Court and the Second Circuit on remand in *Inwood*:

> To establish secondary meaning, a manufacturer must show that in the minds of the public, the *primary significance* of a product feature or term is to

---

[7] *continued*

District Court's finding of "secondary meaning". The appearance identifies the drug product because it is the only visual indication by which the drug may be recognized and identified, and has nothing to do with source. It is the accustomed appearance of the product acquired during the patent monopoly which now identifies the drug to the public, and another appearance does not serve this function. Subjecting doctors and pharmacists to patient inquiries and complaints merely because they prescribe a generic drug creates a barrier to competition, and grants Ciba an undeserved price advantage based on factors unrelated to Ciba as a source, including considerations of safety, patient anxiety and ignorance.

> identify the source of the product rather than the product itself. See *Kellogg Co. v. National Biscuit Co., supra*, at 118. (emphasis added) [456 U.S. 844 at p. 851]

There is no evidence of record that either capsule appearance or the name Apresazide signifies the source of the drug product in suit, rather than the drug itself. On the contrary, all of the witnesses testified that capsule appearance signifies the drug. (see footnote 7, *supra*)

Dr. Silberner testified that patients associate size, shape and color with a certain medicine used for a certain purpose, and that many patients cannot remember the names of their drugs [R. 510-513]. The 55,000 member American Pharmaceutical Association officially recognizes that "patients associate drug identity with drug product appearance" [R. 838]. Dr. O'Donnell testified that "patients associate color of medication with what they are taking it for" [R. 372].

Ciba's own marketing director Kirsch testified that patients associate color with the name and identity of the drug itself rather than the source of the drug [R. 80-81].

Dr. Kriegman, Ciba's other principal witness, confirmed that patients don't associate capsule color with plaintiff as a source [R. 142-143].

Nor can any association of capsule color with the drug name "Apresazide" evidence "secondary meaning". Kirsch testified that "Apresazide" is the common descriptive name of the drug, and that "generic Apresazide" or "Bolar's Apresazide" is the most natural way of referring to Bolar's product in suit [R. 73-74].

Dr. O'Donnell testified that "Apresazide" is necessarily the common descriptive name for the drug because there

is no other useful generic name, and that it is the policy of the Official U.S. Adpoted Names Commission that a combination drug such as Apresazide having multiple ingredients should have a separate generic name [R. 355-361].

Ciba has encouraged physicians to write only the word "Apresazide" on prescriptions, so that this is the only name patients will ever see [R. 1513]. Accordingly, the public *necessarily* uses "Apresazide" as a common descriptive name for the drug, because it is the *only name* provided by Ciba.

A landmark case on this point was *Bayer v. United Drug*, 272 F. 505 (S.D. N.Y. 1921) in which the famous trademark "Aspirin" was at stake. After the patent expired, Bayer sought to enjoin a competitor from using the term "Aspirin". Judge Learned Hand analyzed the case as follows:

> [A]lthough physicians appear to have used the terms, "Aspirin" or "acetyl salicylic acid" indifferently, it cannot be that such patients as read their prescriptions attributed to "Aspirin" any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue. Nor is there any evidence that such as may have seen both terms identified them as the same drug. I cannot speculate as to how many in fact did so. No packages could possibly have reached the consumer, nor was any advertising addressed to them; their only acquaintance with the word was as the name for a drug in whose curative properties they had got confidence. (272 F. 510).

There is no evidence in the record that the general consuming public has had any acquaintance with the term "Apresazide" or the dosage-coding colors of Apresazide

other than as the name or color of a "drug in whose curative properties they had got confidence".

As discussed by Professor McCarthy in his treatise *Trademarks and Unfair Competition* at page 405:

> The name of a product or service itself—what it is—is the very antithesis of a mark. In short, a generic name of a product can never function as a trademark to indicate origin. The terms "generic" and "trademark" are mutually exclusive. As noted previously, the function of a mark is to identify and distinguish the goods or services of one seller from those sold by all others. A mark answers the buyer's question "Who are you? Where do you come from?" But the name of the product answers the question "What are you?" (footnotes omitted)

Ciba selected the name Apresazide to answer the question "What are you" (i.e., "what the product is"). Any association of capsule color with "what the product is" cannot signify Ciba as a source.[8]

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[8] The Court's finding that "Apresazide" is not a generic name simply because Bolar has refrained from using the word to avoid litigation is based on an improper legal standard [R. 704, 718]. In the famous "Cellophane case", defendant's non-use of the trademark "cellophane" did not prevent the word from being generic:

> "In the case at bar the defendant has never used either the words "cellophane" or "DuPont cellophane" with or without the oval, on its goods. It has merely filled orders for cellophane with its own product" [*DuPont Cellophane Company, Inc. v. Waxed Products Co., Inc.*, 30 U.S.P.Q. 332-3329 (1948)]."

Moreover, the Court's finding that Hydralazine Hydrochloride/Hydrochlorothiazide is a generic name does not counter the evidence that Apresazide is also generic and is used generically. A product may have multiple generic names, each of which describes the product in suit. As pointed out by Professor McCarthy in his treatise (*supra*) at page 408:

(Footnote continued on following page)

Where there is no other name for a product, or the only synonym for identifying the specific product is a cumbersome technical term not generally known to purchasers, it is inadequate for use by competitors and will not prevent the mark from being generic. *Anti-Monopoly, Inc. v. General Mills Fun Group, Inc.*, 684 F.2d 1316 (9th Cir. 1982), *cert. den.*, ... U.S. ..... (1983) ("Monopoly"); *DuPont Cellophane Co. v. Waxed Prods. Co.*, 85 F.2d 75 (2nd Cir. 1936) ("Cellophane"); *Haughton Elevator Co. v. Seeberger*, (Com. of Pat. 1950), 85 U.S.P.Q. 80 ("Escalator"); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 (1938) ("Shredded Wheat"); *King Seeley Thermos Co. v. Aladdin Industries, Inc.*, 321 F.2d 577 (2nd Cir. 1963) ("Thermos").

"Apresazide" is the common descriptive name of a prescription drug, and any association of capsule appearance with the name Apresazide, which is the common name of the drug and which is the only name available to patients, cannot show "secondary meaning", 15 U.S.C. §§1064(c), 1065(4).

Common pink/white and blue/white capsules cannot uniquely signify Ciba as a source because they are common in the channels of drug commerce. There is

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[8] *continued*

> There is usually no one, single and exclusive generic name for a product. Any product may have many generic designations. Any one of those is incapable of trademark significance.
>
> * * *
>
> Even if there exists another suitable word to call the product, the public may pick as a generic name the word claimed as a mark by the seller. However, most names become generic because the public is not given any other word to apply to an unfamiliar product. The term which the seller claims is the generic designation other than his "mark", may be so unwieldly and complicated that the public will not accept it. (citations omitted)

nothing special or unique about the colored capsules in suit. There are many drug products of different drug companies having the same or similar appearance as Apresazide [DX 13A, 13B, 14-22; R. 82, 322-323, 800, 802]. Physicians complain that Apresazide capsules look like the earlier-marketed Indocin [R. 1278—DX 65], and Ciba has received complaints that Apresazide looks like the earlier Minipress[9] [R. 782, 786—DX 8, 9]. These complaints confirm the use of capsule color as an identifier of medication and have nothing to do with identification of Ciba as a source.

The identity or confusing similarity of Ciba's capsule colors with those of Minipress, Indocin and many other drugs prevents acquisition of "secondary meaning". By the time Ciba introduced Apresazide, Minipress had been in the marketplace for several months. Both sales and promotional expenditures for Pfizer's Minipress greatly exceed those of Apresazide [R. 93, 1030, 1056—DX 38, 44].

It is hornbook law that a valid trade dress cannot designate multiple sources, and it is accordingly impossible for Ciba to develop any exclusive trade dress rights or secondary meaning in colors of prior products in the same channel of commerce:

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[9] Ciba's own Sales Director Kirsch, when presented with blue/white and pink/white capsules of the earlier marketed Minipress and Dynapen (an antibiotic) confused them with Apresazide and testified that physicians and pharmacists would associate them with Apresazide [DX 6; R. 83-84, 347-348]. Ciba assured the FDA that using the same colors as Minipress was not a problem because the capsule markings were sufficient to prevent confusion as to drug identity [R. 782, 786—DX 8, DX 9]. Here, however, it argues precisely the opposite; that Bolar's markings will not identify Bolar as a source.

> [I]t is vital to the existence of a trade-mark that it should be used by only one concern. A trade-mark cannot serve two masters; it cannot identify two sources at the same time and remain a trademark. [Nims, Unfair Competition and Trademarks, Fourth Edition, Vol. Two, p. 1289].

The lower court's grant of rights in standard capsule colors which were already on the market in the earlier Pfizer product and other drug products used by patients is improper. Such capsule color cannot indicate a "single product from a single source" because it is used for multiple products from multiple sources in the same channel of commerce, any of which might be prescribed for patients taking multiple medications, simultaneously or at different points in time.

The decision below conflicts with the District Court decision in *Inwood*, affirmed by this Court, that mere "copying" of the accustomed appearance of a drug by a generic drug manufacturer, and prior sales of the drug by the former patient holder, do not establish "secondary meaning."

D. The Lower Courts Improperly Based A Nationwide Injunction On New Jersey State Law To Evade This Court's *Inwood* Decision

Bolar manufactured its generic product in New York, having a physical appearance properly approved under Federal law by the United States Food and Drug Administration. Bolar is not located in New Jersey and intentionally avoided all sales of its product into New Jersey. The lower court decisions thus constitute a nationwide enforcement of New Jersey state law in an area preempted by Federal Statute. The decision below applies New Jersey state law, without subject matter jurisdic-

tion over a New York corporation lawfully manufacturing in its own state, to interfere with the generic drug substitution laws of the other states.

The approval of Bolar's product by the U.S. Food and Drug Administration constitutes a Federal Agency determination that Bolar's product is *not* a drug "falsely purporting . . . to be the product of . . . [any] other drug manufacturer . . ." [21 U.S.C. §321(g)(2)]. This determination was made pursuant to specific FDA policy "routinely to approve new drug applications for drug products that duplicate the color, size and shape" of the original product, but not to require such duplication [R. 1586]. Where federal law comprehensively regulates an area of national concern such as the manufacturing of food or drug products, additional regulation by the states of such manufacture and sale, particularly outside their borders, is preempted.[10] *Cloverleaf Butter Co. v. Patterson*, 315 U.S. 148 (1942); see also, *McDermott v. Wisconsin*, 228 U.S 115 (1913); *Campbell v. Hussey*, 368 U.S. 297, 301 (1961); *Pennsylvania R.R. v. The Public Service Commission*, 250 U.S. 566, 568-69 (1919); *Local 174, Teamsters Union v. Lucas Flour Co.*, 369 U.S. 95, 103 (1962); *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 242 (1959).

It is the policy of the various state substitution laws to promote generic substitution. The Attorney General for the State of New York, where Bolar manufactures its product, strongly favored generic drugs in the accustomed

[10] In addition, New Jersey is precluded by the overriding policy of the patent laws from preventing Bolar from copying and selling the previously patented product in its accustomed form. *Compco Corp. v. Day Brite Lighting, Inc.*, 376 U.S. 238 (1964); *Sears, Roebuck & Co. v. Stiffel Company*, 376 U.S. 225 (1964).

drug color in his *Amicus* brief in *Inwood*. That the various state substitution laws are frustrated by preventing uniformly colored generic products is pointed out by Justice White's concurring opinion in the *Inwood* case:

> Preventing the use of generic drugs of the same color to which customers had become accustomed in their prior use of the brand name product interferes with the important state policy, expressed in New York and 47 other states, of promoting the substitution of generic formulations. [456 U.S. 844 at 861]

The lower court's injunction frustrates the various state substitution laws, and is an improper regulation of interstate commerce prohibited by the Constitution.

E. The Decision Below Granting Exclusive Trade Rights From Illegal Drug Sales And Promotion Is In Conflict With The Decisions Of This Court And The Other Circuits

The decisions below establish a dangerous precedent by permitting the acquisition of exclusive trade rights solely from illegal drug marketing activities [R. 469-480]. As earlier discussed, sales of Apresazide relied on by the lower courts to prove secondary meaning included sales of an adulterated drug, and all of Ciba's promotion evidence, relied on by the lower courts as proof of "secondary meaning", was illegally designed to mislead physicians into believing that Apresazide is recommended as "second step" therapy by the prestigious National High Blood Pressure Education Program Task Force. 21 U.S.C. §§351, 352(e),(n).

To prevent "profit when generic names cannot be remembered" [R. 952; DX 31], and to insure that useful generic names for drugs are in the public domain, Congress required that *all prescription drug advertisements*

have a generic name printed in type half as large as any corresponding brand name [21 U.S.C. §§ 352(e),(n); R. 870-72]. Ciba has also intentionally violated the generic name promotion law in all of its advertisements. The penalty for false advertising and for failure to comply with the generic name labelling requirement is that Ciba's Apresazide is "deemed misbranded" and is not legally in commerce. 15 U.S.C. §§331, 352. *United States v. Urbuteit*, 335 U.S. 355 (1948).

This Court has never permitted acquisition and enforcement of exclusive rights in a drug based on misrepresentation to the public of the nature of the product. *Morton Salt Co. v. Suppinger*, 314 U.S. 488 (1942); *Worden v. California Fig Syrup Co.*, 187 U.S. 516 (1902); *Manhattan Medicine Co. v. Wood*, 108 U.S. 218 (1882). Misbranded and adulterated drugs such as Ciba's Apresazide are not legally "in commerce" for purposes of the trademark laws because tradermark rights, either at common law or under the Lanham Act, are acquired and maintained only by lawful use, and the grant of exclusive trade rights cannot be based on such illegal use. *Strey v. Devine's, Inc.*, 217 F.2d 187 (7th Cir., 1954); *Cameo, Inc. v. Plough, Inc.*, 185 U.S.P.Q. 228 (N.D. Ohio 1975); *In re Stellar International Inc.*, 59 U.S.P.Q. 48 (TTAB 1968); *Clairol Incorporated v. Holland Hall Products, Inc.*, 165 U.S.P.Q. 214 (TTAB 1970); *In re Taylor*, 133 U.S.P.Q. 490 (TTAB 1962).

The reliance by the courts below on illegal marketing and drug sales establishes a dangerous precedent which should be reviewed by this Court.

CONCLUSION

It is respectfully submitted that a Writ of Certiorari should issue to review the decisions below against manufacture of generic drugs in publicly accustomed form. The decisions adversely affect competition in the drug industry, and transcend the interests of the litigants.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

APPENDIX TO THE PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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In The

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UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 82-5797

CIBA-GEIGY CORPORATION,

Appellee

v.

BOLAR PHARMACEUTICAL CO., INC.,

Appellant

Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil No. 82-00788)

ARGUED JUNE 16, 1983

Before: HUNTER and HIGGINBOTHAM,
Circuit Judges, and GILES,*
District Judge.

(Opinion Filed October 14, 1983)

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* Honorable James T. Giles, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

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OPINION OF THE COURT

Per Curiam

CIBA-GEIGY Corporation ("Ciba") initiated this action on March 12, 1982, alleging that Bolar Pharmaceutical Co., Inc. ("Bolar") had violated Section 43(a) of the Lanham Trade-Mark Act, 15 U.S.C. § 1125(a) (1976) and two independent torts under New Jersey Law, "unprivileged imitation" and "passing off," by copying the trade dress of Ciba's APRESAZIDE products.

Following a lengthy hearing, the district court, relying primarily on *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), granted preliminary injunctive relief. The injunctive relief prevented Bolar from "using any simulation, imitation or substantial duplication of [Ciba's] distinctive trade dress . . . in connection with . . . [Bolar's] hydrolazine hydrochloride/hydrochlorothiazide products for the treatment of hypertension." IV Appendix (App.) 727. The district court based its grant of injunctive relief on its belief (1) that Ciba "demonstrate[d] a likelihood of ultimate success as to at least one of the [counts—either the Lanham-Act count of the State unfair-competition counts]; (2) that Ciba "is threatened with irreparable injury absent such relief;" and (3) "that the balance of equities and the public interest favor such relief." IV App. at 709. Appellant Bolar argues that the district court abused its discretion and made various errors in its findings of fact and conclusions of law. But, we find no merit to appellant's arguments seeking to overturn the grant of a preliminary injunction.

The narrow scope of review of a district court's grant of an application for preliminary injunctive relief permits us to dissolve an injunction only if

> the trial court abuses [its] discretion, commits an obvious error in applying the law, or makes a serious mistake in considering the proof . . . .

SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d at 1066, quoting *A.O. Smith Corp. v. FTC*, 530 F.2d 515, 525 (3d Cir. 1976). See *Scooper Dooper, Inc. v. Kraftco Corp.*, 460 F.2d 1204 (3d Cir. 1972). Thus, an appellant who is attempting to overturn a district court order granting (or denying) a preliminary injunction carries a heavy burden. *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d at 1066; *See, Oburn v. Shapp*, 521 F.2d 142, 147 (3d Cir. 1975); *Scooper Dooper, Inc. v. Kraftco Corp.*, 460 F.2d at 1205.

After reviewing the record, the briefs and arguments of the parties, and Judge Sarokin's thoughtful and detailed opinion, we hold that the district court did not abuse its discretion, commit an obvious error in applying the law,[1] or make a serious mistake in considering the proof.

Accordingly, we will affirm the district court's grant of a preliminary injunction.

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[1] Appellant also argues that the district court erred in failing to read Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc., ("Ives"), ... U.S. ....., 102 S.Ct. 2182, 2290 (1982), as overruling the reasonable anticipation standard in SK&F Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055 (3d Cir. 1980) for the tort of "passing off" under § 43(a) of the Lanham Act. However, we need not address this issue because the district court's conclusions regarding the New Jersey state law claims of "passing off" and "unprivileged imitation" are mandated by *SK&F* and provide a sufficient independent basis for affirming the district court's grant of preliminary injunctive relief.

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Third Circuit

Filed October 4, 1982

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant.

Civil Action No. 82-788

ORDER

This matter having been opened to the court by Pitney, Hardin, Kipp & Szuch (Frederick L. Whitmer, Esq. appearing) and by Kaye, Scholar, Fierman, Hays & Handler (Randolph S. Sherman, Esq. appearing), attorneys for plaintiff CIBA-GEIGY Corporation ("CIBA-GEIGY"), and in the presence of Bendit, Weinstock & Sharbaugh (James F. Keegan, Esq. appearing) and Fitch, Even, Tabin, Flannery & Welsh (Robert B. Jones, Esq. appearing), attorneys for defendant Bolar Pharmaceutical Co., Inc. ("Bolar"), and the court having held meetings on April 22, May 12, and June 15, 1982 on plaintiff's motion for preliminary injunction, and the court having heard and considered the evidence and the arguments of counsel, and for the reasons set forth in the Opinion filed by the court on August 11, 1982, and good cause appearing;

It is on this 4 day of October 1982,

ORDERED that CIBA-GEIGY's motion for preliminary injunction be granted, and

A. IT IS FURTHER ORDERED that for the purpose of this preliminary injunction and pending final adjudication, the plaintiff's trade dress for its Apresazide products is described as size 3 capsules having a blue and white opaque color combination, size 2 capsules having a pink and white opaque color combination, and size 1 capsules having a pink flesh and white opaque color combination. Attached hereto and made a part hereof is a photograph, designated Exhibit A, showing the respective colors and shapes (but not the sizes) of the capsules.

B. IT IS FURTHER ORDERED that Bolar Pharmaceutical Co., its officers, directors, agents, employees, servants, attorneys, and all those in active concert or participation with any of the foregoing who receive actual notice of this Order by personal service or otherwise, are hereby preliminarily enjoined, from in any manner, directly or indirectly,

(1) using any simulation, imitation or substantial duplication of plaintiff's distinctive trade dress as described in paragraph (A) of this order in connection with promoting, advertising, selling, offering for sale, marketing, distributing or otherwise placing in the channels of trade any hydrolazine hydrochloride/hydrochlorothiazide products for the treatment of hypertension.

and

C. IT IS FURTHER ORDERED that defendant shall serve a copy of this Order upon all wholesalers, distributors, jobbers, pharmacists and others to whom said product has been sold by defendant or by those in active concert or participation with defendant.

/s/ H.Lee Sarokin
U.S.D.J.

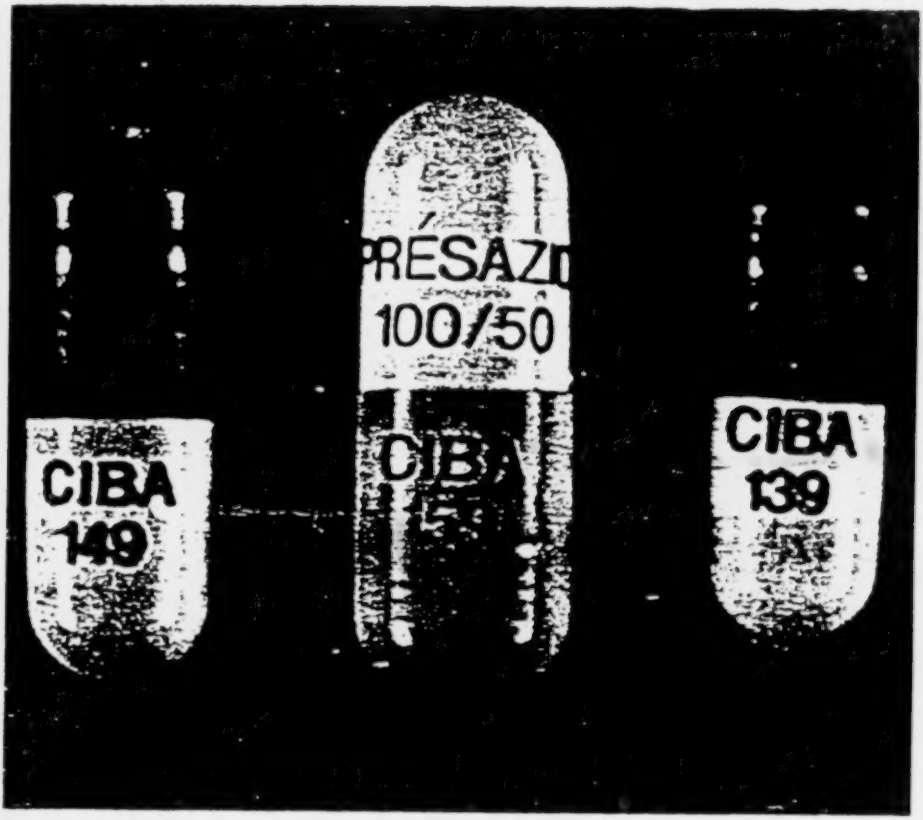

EXHIBIT A

Filed August 11, 1982

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant.

Civil Action No. 82-788

OPINION

SAROKIN, *District Judge*

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INTRODUCTION

Although the battle over "look-alike" drugs raises difficult legal issues, the realities of these repeated skirmishes should not be ignored. The brand name companies have spent years and substantial monies in developing and promoting their product. They not only create the drug but establish a market for it. By virtue of their advertising campaigns, doctors become aware of the drug and its benefits and are encouraged to prescribe it.

The generic "look-alike" drug enters the marketplace with a substantial advantage. The predecessor manufacturer has performed the necessary research and development and has created the market. Therefore, the generic drug can be produced and sold at a much lower cost. The "look-alike" drug becomes more saleable, because it makes it easier for both the doctor and pharmacist to substitute the generic drug. A patient who has utilized the brand name drug over a period of time may accept the generic drug more readily if it looks the same as the brand name. The patient may resist such substitution, if it does not. Most often that anxiety can be dispelled by a simple explanation by the physician or pharmacist regarding the substitution of a generic drug with a different appearance.

On the other hand, the brand name manufacturer contends that the identity of appearance facilitates negligent and intentional substitution without authorization from either the doctor or the patient. To permit the generic drug to copy the appearance of the brand name product increases sales by the generic manufacturer and erodes those of the brand name manufacturer. Although both seek to rest their cause on the public good, it is profit and the desire to earn it which is at the core of this dispute. The generic manufacturer wishes to benefit from the efforts and expense of the brand name manufacturer. The latter wishes to prevent and prohibit such intrusion and retain the benefits for itself.

With this general introduction the court will consider the specific factual and legal issues presented by this matter.

PROCEDURAL HISTORY

Plaintiff CIBA-GEIGY Corporation ("CIBA-GEIGY") commenced this action on March 12, 1982, alleging that defendant Bolar Pharmaceutical Co., Inc. ("Bolar") had violated both the federal and state law of unfair competition by intentionally duplicating the physical appearance (i.e., trade dress) of CIBA-GEIGY's brand name prescription drug APRESAZIDE.® On March 17, 1982, following notice to Bolar, the defendant was temporarily restrained from selling its generic versions of the products in suit in trade dress confusingly similar to that of CIBA-GEIGY's APRESAZIDE products and Bolar was ordered to show cause on March 22, 1982, why such conduct should not be preliminarily enjoined.

Bolar then moved to dismiss the complaint for lack of personal jurisdiction and improper venue. On March 22, 1982, in order to permit development of the jurisdictional facts relative to Bolar's New Jersey contacts and to enable both parties to conduct discovery attendant to CIBA-GEIGY's preliminary injunction motion, the court adjourned the hearing until April 22, 1982 and, with Bolar's consent, continued the temporary restraining order until that date. On April 21, 1982, Bolar advised the court that it was withdrawing its motions.[1]

[1] CIBA-GEIGY seeks its costs, including attorney's fees, for defending against Bolar's motions on the ground that they were baseless when made and interposed solely for purposes of vexation. Consideration of that application has been deferred pending resolution of the preliminary injunction motion.

Evidence with respect to the preliminary injunction motion was taken on April 22, May 12 and June 15, 1982.[2] CIBA-GEIGY called three witnesses as part of its affirmative case and two rebuttal witnesses; in addition, plaintiff introduced numerous exhibits into evidence, including designated portions of two depositions. Bolar called three witnesses as part of its defense and introduced numerous exhibits into evidence. As to all exhibits accepted into evidence, the court reserved ruling on relevancy objections pending review of the parties' post-hearing submissions, and repeatedly observed that its determination would be based only upon relevant and material evidence.[3]

The temporary restraining order was continued through the May 12 hearing upon Bolar's consent. Thereafter, upon good cause shown, the court continued the order over Bolar's objection.

The following findings of fact and conclusions of law are based upon a careful review of the entire record, an appraisal of the witnesses' credibility and demeanor and the reasonable inferences to be drawn therefrom, the proposed findings of fact submitted by both parties.

FINDINGS OF FACT

A. *The Parties*

CIBA-GEIGY, a New York corporation with a principal place of business in Summit, New Jersey, is engaged, among other things, in the research, development, manufacturer and sale of prescription pharmaceutical products, and in particular the research and development of new prescription drugs for the treatment of hypertension (commonly referred to as high blood pressure). CIBA-GEIGY

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[2] Neither party consented under Rule 65(a)(2) of the Federal Rules of Civil Procedure to advance and consolidate the trial on the merits with the hearing on CIBA-GEIGY's preliminary injunction.

[3] The opinion of the court conforms to that understanding.

devoted a significant portion of its annual research and development budget to research specifically directed at the treatment of hypertension.

CIBA-GEIGY markets brand name pharmaceutical products through two separate divisions, the CIBA Pharmaceutical Company and GEIGY Pharmaceuticals, each having responsibility for the marketing and sale of its own product line. The CIBA Pharmaceutical Company currently markets approximately forty-one prescription pharmaceuticals, ten of which are prescribed for the treatment of hypertension (*i.e.*, anti-hypertensives). The promotion of these products is carried on throughout the United States through a network of some 400 CIBA sales representatives, thirty eight district sales managers, and six regional sales managers. The sales representatives, also known as detail men, personally call upon physicians, retail pharmacists and hospital pharmacies to promote the CIBA line of products through the use of written brochures, reminder or "leave" items (such as pens, rulers and scratch pads) and free drug samples. CIBA-GEIGY does not generally advertise its prescription products directly to the consumer.

Bolar, a New York corporation with its principal place of business in Copiague, New York, is what is known in the pharmaceutical industry as a generic drug manufacturer; that is, it makes and markets under generic names, prescription pharmaceuticals which duplicate the active ingredients of products already researched, developed and sold under brand name by companies such as CIBA-GEIGY. Because their research, development and clinical expenses are generally much less than those of brand name companies, generic drug manufacturers are usually able to sell their products at prices lower than their brand name counterparts.[4]

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[4] In the case of the product in suit, Bolar and CIBA-GEIGY each obtained approval from the Food and Drug Administration by the same Abbreviated Drug Application (ANDA) Procedure [21 C.F.R. 314.1(f)].

Bolar markets its generic pharmaceuticals directly to approximately 400 active customers throughout the United States. These customers are comprised of private label distributors, drug wholesalers and distributors, and federal government agencies. Bolar does not sell its product directly to retail pharmacies; rather, pharmacies purchase Bolar's products through drug wholesalers and distributors which, in turn, buy directly from Bolar. Nor does Bolar promote its generic products directly to physicians and pharmacists, as does CIBA-GEIGY. It is primarily the promotional effort by brand name companies which creates the demand for new prescription drugs.

B. *CIBA-GEIGY's APRESAZIDE Products*

In 1959, CIBA-GEIGY, with the approval of the Food and Drug Administration ("FDA") began manufacturing and selling a combination prescription drug under the registered trademark APRESOLINE-ESIDRIX for the treatment of hypertension. CIBA-GEIGY's APRESOLINE-ESIDRIX product, which it makes and markets in orange, dry-coated tablets, contains two active ingredients: hydralazine hydrochloride and hydrochlorothiazide, in a fixed ratio of 25 mg. to 15 mg. per tablet.

Two factors often responsible for hypertension are vasoconstriction (i.e., constriction of the blood vessels) and excessive fluid volume. Hydrochlorothiazide is a diuretic which reduces excess sodium and fluid volume. However, because hydrochlorothiazide basically treats only the excessive fluid problem, it often proves therapeutically inadequate once hypertension has progressed beyond its milder forms. Hydralazine hydrochloride is a vasodilator which treats vasoconstriction by directly relaxing and dilating arterioles, thereby decreasing peripheral resistance. By combining hydralazine hydrochloride and hydrochlorothiazide, both factors can be treated in a single product. In obtaining FDA approval to market its APRESOLINE-ESIDRIX product, CIBA-GEIGY became the first drug manufacturer to establish the safety and efficacy

of a fixed combination of hydralazine hydrochloride and hydrochlorothiazide for the treatment of hypertension. Subsequent to CIBA-GEIGY's introduction of its APRESOLINE-ESIDRIX product, other drug companies, including Bolar, began selling a combination of 25 mg. of hydralazine hydrochloride and 15 mg. of hydrochlorothiazide in tablet form.

In 1974, faced with the possible market withdrawal or decreased sales of its leading anti-hypertensive product SER-AP-Es, due to an alleged link between one of its active ingredients, reserpine, and breast cancer, CIBA-GEIGY determined that hydralazine hydrochloride, alone and in combination with hydrochlorothiazide, offered the company "the greatest promotional opportunity in a non-reserpine antihypertensive market." In the fall of 1974 CIBA-GEIGY commenced developmental efforts ultimately to bring to market dosage strengths of hydralazine hydrochloride and hydrochlorothiazide in fixed combination ratios of 25 mg./25 mg., 50 mg./50 mg. and 100 mg./50 mg.

In September 1974, CIBA-GEIGY determined, for marketing reasons, that these new combination ratios of hydralazine hydrochloride and hydrochlorothiazide should be made and sold in capsule rather than tablet form. The selection of these products' trade dress was made in order to distinguish the new products from CIBA's other hydralazine-containing products then on the market, all of which, including the APRESOLINE-ESIDRIX product, were being sold in tablet form. There was no medical, pharmaceutical or manufacturing reason which compelled CIBA-GEIGY to make the new combinations in capsule rather than tablet form.

CIBA-GEIGY also selected the capsule color for its new hydralazine hydrochloride/hydrochlorothiazide formulations in September 1974. The initial recommendations were made by Mr. John S. Marmaras, CIBA Pharmaceutical's Design Director at the time. Mr. Marmaras chose color combinations which were "pleasing" to his eye, and then

recommended them to CIBA's Marketing Department for Mr. Barnes' ultimate approval. Two criteria were used in making the ultimate selection: first, the capsule colors should not duplicate those of any other currently marketed major pharmaceutical product; and, second, they should not be displeasing to the eye. The capsule colors which were selected were those in which CIBA-GEIGY eventually marketed its new hydralazine hydrochloride/hydrochlorothiazide combinations under the brand name APRESAZIDE: (a) blue and white opaque combination capsules containing 25 mg. of hydralazine hydrochloride and 25 mg. of hydrochlorothiazide; (b) pink and white opaque capsules containing 50 mg. of hydralazine hydrochloride and 50 mg. of hydrochlorothiazide; and (c) pink flesh and white opaque capsules containing 100 mg. of hydralazine hydrochloride and 50 mg. of hydrochlorothiazide. As in the case of capsule selection, CIBA-GEIGY arbitrarily selected these color combinations based solely on marketing considerations; there was no medical, pharmaceutical or manufacturing reason which compelled the selection of these particular capsule colors.

On May 26, 1976, CIBA-GEIGY obtained FDA approval in the form of an approved Abbreviated New Drug Application ("ANDA") to market its new hydralazine hydrochloride/hydrochlorothiazide combinations. Thereafter, in October 1976, CIBA-GEIGY began to sell these combination products under the brand name APRESAZIDE for the treatment of hypertension. On February 15, 1977, CIBA-GEIGY was granted a federal registration for the trademark APRESAZIDE; and on March 9, 1982, CIBA-GEIGY filed a declaration under Sections 8 and 15 of the Lanham Act (15 U.S.C. §§ 1058, 1065) with the Commissioner of Patents and Trademarks.

Since October 1976, CIBA-GEIGY has continuously marketed its APRESAZIDE products in the same trade dress, and for over five years, from October 1976 to March 1982, it was the sole pharmaceutical company which

marketed these combination products in the particular trade dress described.[5]

From October 1976 to date, CIBA-GEIGY, through its CIBA Pharmaceutical Company division, has spent and continues to spend substantial sums of money advertising and promoting its APRESAZIDE products to physicians, pharmacists and hospitals. During the period October 1976 through 1981, CIBA-GEIGY's expenditures for the distribution of free samples and for promotional and medical literature, films, symposia and seminars promoting its APRESAZIDE products were in excess of $9 million. In addition, during this same period, the cost attributable to the efforts of the CIBA Pharmaceutical Company sales force in promoting APRESAZIDE products was over $16 million.

Since October 1976, CIBA-GEIGY's promotional literature for its APRESAZIDE products, including detailing folders and reminder or "leave" items, has routinely featured the capsules' physical appearance in pictures as well as described them in words. In addition, CIBA-GEIGY has promoted its APRESAZIDE products by distributing free sample capsules to physicians.

CIBA-GEIGY's sales of these combinations have increased steadily and substantially since their market introduction in October 1976. From that time through 1981, CIBA-GEIGY's total annual dollar sales of its APRESAZIDE products increased as follows:

1976 (Oct. - Dec.)	$ 1.1 million
1977	$ 3.4 million
1978	$ 5.3 million
1979	$ 8.3 million
1980	$11.2 million
1981	$14.3 million

[5] Until February 1982, CIBA-GEIGY was the only pharmaceutical manufacturer with FDA approval to market these particular combinations of hydralazine hydrochloride/hydrochlorothiazide at all, regardless of trade dress.

CIBA-GEIGY projects that in 1982 its APRESAZIDE sales will rise to approximately $17 million.

Similarly, from October 1976 through 1981, CIBA-GEIGY's annual APRESAZIDE sales in terms of capsules increased as follows:

	Blue & White 25 mg./25 mg.	Pink & White 50 mg./50 mg.	Pink Flesh & White 100 mg./50 mg.
1976 (Oct.-Dec.)	7,441,000	4,645,500	1,076,000
1977	34,480,800	9,611,100	945,100
1978	50,013,500	14,059,100	1,354,800
1979	70,706,100	19,363,900	1,699,800
1980	83,019,400	22,310,400	1,838,500
1981	90,939,700	23,673,600	1,946,100

Bolar's decision to market generic versions of the APRESAZIDE combinations was based, at least in part, on the commercial success that CIBA-GEIGY had achieved with those products.

From October 1976 through 1981, the number of patients taking APRESAZIDE products for hypertension also increased steadily.

As a result of their commercial success, CIBA-GEIGY's APRESAZIDE products have become the third largest seller in the CIBA Pharmaceutical line of ten anti-hypertension products and the fifth largest seller in the entire CIBA Pharmaceutical line of forty-one prescription products.

As a result of CIBA-GEIGY's long, continuous and exclusive use of the trade dress for its APRESAZIDE products, its extensive promotional efforts and the commercial success that its APRESAZIDE products have achieved, physicians who regularly prescribe APRESAZIDE products have come to associate the trade dress of those capsules with the brand name APRESAZIDE as representing a single source of supply. Moreover, because anti-hypertensive drugs are usually taken on a daily basis for an extended period of time and because the

medication's name is routinely typed or written by the pharmacist on the patient's vial, many patients taking APRESAZIDE products have come to associate the trade dress of those capsules with the brand name APRESAZIDE as representing a single source of supply although not with the particular manufacturer.

C. *Bolar's Look-Alike Products*

On March 4, 1982, Bolar received FDA approval in the form of an approved ANDA to market combination products containing hydralazine hydrochloride and hydrochlorothiazide in the same fixed ratios as CIBA-GEIGY's APRESAZIDE products. The ANDA's approved labeling indicated that Bolar intended to market these combinations in the same colors, sizes and shapes as CIBA-GEIGY's APRESAZIDE capsules.

Although Bolar claims that it selected its colors for reasons of public safety and public recognition, the court finds that Bolar deliberately copies the trade dress of CIBA-GEIGY's APRESAZIDE capsules for its own economic advantage.

Bolar claims that it copied the trade dress of CIBA-GEIGY's APRESAZIDE products in order to prevent injury and confusion on the part of patients who it claims identify the trade dress of their medications with the particular medical conditions for which they are prescribed. Wholesale and distributor customers would prefer Bolar to duplicate the trade dress of CIBA-GEIGY's APRESAZIDE products because doing so will facilitate generic substitution and thus increase the sales of Bolar's products. Patients are more apt to accept generic substitutions if the medication has the same appearance. They may reject such substitution if it does not. The court specifically finds that Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide combinations at the expense of CIBA-GEIGY's APRESAZIDE products.

D. *Likelihood of Confusion*

Bolar contends that the imprintation of its corporate logo and NDC Code Number on each of its hydralazine hydrochloride/hydrochlorothiazide capsules sufficiently distinguishes them from CIBA-GEIGY's APRESAZIDE capsules so as to obviate any likelihood of confusion among patients.

Realistically, the likelihood of confusion cannot be assessed by a side-by-side comparison of the plaintiff's and defendant's products. It is the overall physical appearance of defendant's trade dress which is critical. The vast majority of patients who take this type of medication do not or cannot identify their medication, or its source, by reference to the matter imprinted on the drug capsule or tablet. Most of such patients are over the age of 60 years and it is unlikely that they will have sufficiently acute eyesight to detect the difference between their usual medication and Bolar's products based on the imprintations on Bolars' capsules.

Furthermore, Bolar's contention is contrary to its assertion that such duplication will obviate patient resistance to lawful generic substitution. Indeed if patients would be able to distinguish the source by markings on the capsule itself, it is difficult to reconcile that contention with the claim that copying of the characteristics facilitates lawful substitution. On the one hand defendant asserts that copying reduces resistance because the patient will think he or she is receiving the same medication. On the other hand and quite inconsistently, defendant contends that the medications can be readily distinguished by examination of the capsule. The fact is that they cannot be so distinguished by the typical patient utilizing such medication.

E. *Nonfunctionality of APRESAZIDE's Trade Dress*

There was no medical, pharmaceutical or manufacturing reason which compelled Bolar to make its hydralazine hydrochloride/hydrochlorothiazide combinations in capsule

rather than tablet form or in the same color combinations as CIBA-GEIGY's APRESAZIDE products. CIBA-GEIGY's APRESOLINE-ESIDRIX product, containing 25 mg. of hydralazine hydrochloride and 15 mg. of hydrochlorothiazide, is made in tablet form, as is Bolar's generic version of this product. CIBA-GEIGY actually formulated and manufactured production batches of the products at issue here in tablet form.

Another drug manufacturer, Reid-Provident Laboratories, Inc. ("Reid-Provident"), is marketing its products in distinctively different colored capsules than APRESAZIDE and has been successfully marketing its green-colored capsules as generic alternatives to CIBA-GEIGY's APRESAZIDE products.

Since the commencement of this action, Bolar itself has been marketing the fixed combinations in suit in distinctly different colored capsules than CIBA-GEIGY's APRESAZIDE products; and Bolar admits that such sales will be profitable. However, such action may have resulted from the temporary restraining order in this matter. Accordingly, the court does not view it as appropriate to utilize such sales in determining this matter, since the alternative may have been necessitated by compulsion.

The FDA has taken the official position that "the appearance of drug products is [not] closely enough related to their safety and effectiveness that the Agency can, on the basis of its present experience, require that generic drug products duplicate the appearance of their innovator drug counterparts." Although the FDA has routinely approved new drug applications and abbreviated new drug applications for drug products that duplicate the color, size and shape of the innovator's product, it has declined to *require* such duplication and "has not taken action affirmatively to encourage similarity in appearance between innovator products and their generic versions."

The official position of the New Jersey Drug Formulary is that a drug's trade dress serves no therapeutic function. Thus, in a section addressed "To the Consumer," the Formulary states:

> You should understand that generic products often differ in color, shape or size from the better-known (and usually more expensive) brand name products. Such differences are to be expected; these differences do *not* affect how well the medication works.

The court specifically rejects the contentions by Bolar that CIBA-GEIGY's trade dress is functional because it distinguishes between strengths; or because it may be used for preliminary identification in overdose or poison incidents; or because it may be a secondary means of identification by pharmacists.

Bolar's principal functionality contention is that patients with chronic illnesses such as hypertension identify the trade dress of their medications with the medical condition for which they are prescribed and that, accordingly, it is necessary for general equivalents to duplicate the physical appearance of their brand name counterparts in order to prevent patient confusion and anxiety where legal generic substitution occurs.[6]

This resistance or anxiety theory has no application in cases where a patient is prescribed a particular medication for the first time and his pharmacist lawfully dispenses the generic equivalent. In such instances, even if the generic equivalent looks different than its brand name counterpart, the patient will neither be confused nor anxious since he or she has never been exposed to the brand name product's trade dress. To the extent that the patient in such circumstances identifies his medication's physical appearance with the condition for which it has been prescribed, he or she will do so by reference to the generic equivalent's trade dress.

Similary such theory has no application in cases where a patient who is already on a brand-name drug is given

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[6] The court has already noted the inconsistency of this position with the claim that Bolar's product is readily distinguishable by virtue of its own markings on the capsule.

the opportunity to switch to a generic equivalent but declines to do so. In these situations, which concededly occur and are consistent with the patient's right to exercise informed consent, the physician or pharmacist will honor the patient's preference and continue the patient on the brand-name product. Thus, there is no occasion for confusion or anxiety under these circumstances based on differences in trade dress because the patient is never dispensed the generic equivalent, and therefore no anxiety or resistance can develop.

Accordingly, the theory is applicable only to those cases in which generic substitution is authorized, and a patient already on a brand name product is then dispensed a different-looking generic equivalent. In this situation, the patient will usually call his physician or pharmacist to inquire whether the correct medication has been dispensed. However, the two physicians who testified at the hearing, Dr. Audrey G. Kriegman of CIBA-GEIGY and Dr. Herbert Silberner, Bolar's own expert, both agreed that as soon as the situation is explained to the patient (which is standard medical and pharmacy practice) the patient invariably accepts the explanation and his temporary anxiety is immediately dissipated.

If the fears and anxieties of the patient could not be quelled by such an explanation, it may well be that a finding of functionality would be mandated. For this reason, the court made specific inquiry of Bolar's expert on this very subject:

> THE COURT: . . . [S]uppose, for instance, the generic equivalent was a different size, color and shape than a brand name drug; what difference would that make?
>
> THE WITNESS: The difference would be primarily if he were to change from one drug to another. In other words, if the brand name were one size, shape and color and the generic were another, when he made the transformation from the brand name to the generic there would be an element of con[f]usion.

THE COURT: But that could be remedied, could it not, by your explaining to the patient that he or she was receiving the generic equivalent?

THE WITNESS: That is exactly what we have to do, yes, sir.

THE COURT: And has that, in your experience, satisfied the patient's hesitancy?

THE WITNESS: Once the patient has been explained, they will accept the different size, shape and color. But it requires an explanation.

In order to exercise informed consent to generic substitution, a patient is entitled to know in advance whether the generic equivalent is made by a different drug manufacturer than the brand name counterpart he has been taking.[7]

Bolar's entire theory rest on the improper assumtion that the patient will develop resistance or anxiety upon receiving a different looking pill than that which had previously been prescribed. That assumption does not accord with the facts or with the law in many states. As a matter of practice or requirement, either the physician or the pharmacist will advise the patient of the proposed generic substitution in advance. It would be a simple matter to advise the patient at the time that the medication may be different in appearance. Such procedure could assuage the patient before ever examining the medication and recognizing the change in appearance. The same result is accomplished if the difference in appearance is discovered for the first time after the generic drug is dispensed and the explanation follows rather than precedes receipt of the medication. The right of informed consent will be jeopardized if the generic equivalent looks identical or confusingly similar to the brand name drug, since Bolar's theory necessarily assumes that in such cir-

[7] The Illinois Formulary specifically provides that drug substitution may not occur unless, *inter alia*, the "informed" patient agrees to the substitution.

cumstances the patient will not be alerted to any difference in the two products.

Permitting generic drug manufacturers to sell identical copies of medication may deprive patients of the right to make such inquiry because they will be deprived of the opportunity to be informed of the facts (i.e. the difference in appearance) sufficient to warrant such inquiry. Therefore, the court rejects Bolar's functionality argument as being unsupported by the record and contradicted by the testimony of its own expert witnesses.

F. *Secondary Meaning*

Applying the well-settled legal criteria for determining secondary meaning to the court's foregoing fact findings concerning (a) the extended, continuous and exclusive use by CIBA-GEIGY of APRESAZIDE's trade dress; (b) the extensive and costly activities of CIBA-GEIGY in promoting its APRESAZIDE products and their distinctive and arbitrary trade dress; (c) the commercial success that CIBA-GEIGY's APRESAZIDE products have achieved in the market place; and (d) Bolar's intentional copying of APRESAZIDE's trade dress and the motivation for that copying, the court finds that CIBA-GEIGY has demonstrated a strong likelihood of ultimate success.

Bolar has advanced several arguments in opposition to CIBA-GEIGY's assertion that the trade dress of its APRESAZIDE products has acquire secondary meaning: *first*, that the mere existence of other blue and white, pink and white and pink flesh and white capsules on the market, albeit for non-antihypertensives and regardless of their sizes, shapes and shades, precludes a finding of secondary meaning in APRESAZIDE's trade dress; *second*, that in September 1974, CIBA-GEIGY allegedly copied the trade dress of Pfizer's yet to be marketed MINIPRESS products, at least for the blue and white 25 mg./25 mg. and the pink and white 50 mg./50 mg. APRESAZIDE capsules; *third*, that even if CIBA-GEIGY did not copy MINIPRESS's trade dress, the prior market

presence of Pfizer's blue and white 5 mg. and pink and white 2 mg. of MINIPRESS capsules, which are antihypertensives, precludes a finding of secondary meaning in the trade dress of CIBA-GEIGY's 25 mg./25mg. and 50 mg./50 mg. products; and *fourth*, that APRESAZIDE has become the common, descriptive name for all combinations of hydralazine hydrochloride and hydrochlorothiazide in the same fixed ratios as the products in suit or, alternatively, that CIBA-GEIGY has abandoned its federally-registered APRESAZIDE trademark.

1. *The Existence of Non-Antihypertensives Having the Same General Color Scheme as APRESAZIDE Capsules.*

Dr. O'Donnell conducted a survey of drug literature for Bolar, in the course of which he identified about fifty drug products appearing in blue and white capsules, about eight to ten appearing in pink and white capsules, and approximately two appearing in pink flesh and white. Bolar introduced only certain of these capsules into evidence at the hearing. While accepting their admission into evidence over the objection of CIBA-GEIGY's counsel, the court stated at the time that it was dubious about their probative significance. The court finds that these exhibits and the survey are irrelevant to the issues before the court and, hence, are entitled to no weight on this motion except for the MINIPRESS capsules, which shall be discussed hereafter. All other capsules clearly involve the proverbial comparison of "apples and oranges." Firstly, many of the identified capsules were either distinctly different shades of blue or pink or distinctly different sizes than CIBA-GEIGY's APRESAZIDE capsules. Secondly, Dr. O'Donnell admitted that not one of the ten exhibits contained active ingredients which were chemically, generically or pharmaceutically equivalent to those of APRESAZIDE products; and that, in fact, unlike APRESAZIDE products, not one of these exhibits was a product indicated for the treatment of hypertension. Indeed, two of the

products (Anacin-3 and Extra Strength Bufferin) are not even prescription drugs. None of these products could legally be substituted for APRESAZIDE products, even when the physician's prescription permits substitution.

2. *CIBA-GEIGY's Alleged Copying of MINIPRESS's Trade Dress*

Pfizer's MINIPRESS product is a prescription drug indicated for the treatment of hypertension which contains a single active ingredient, prazosin hydrochloride. MINIPRESS is marketed in a 1 mg. all-white capsule, a 2 mg. pink and white capsule, and a 5 mg. blue and white capsule. (D-1, D-2, D-12A). Bolar contends that in selecting the trade dress for its 25 mg./25 mg. and 50 mg./50 mg. APRESAZIDE products, CIBA-GEIGY deliberately copied the trade dress of Pfizer's 5 mg. and 2 mg. MINIPRESS products, thus negating a finding of secondary meaning. Although there is substantial evidence that CIBA-GEIGY carefully followed, investigated and monitored Pfizer's progress with said product, there is no evidence that CIBA-GEIGY deliberately copied the trade dress of any of Pfizer's capsules for MINIPRESS.

CIBA-GEIGY selected the capsule form and colors for its APRESAZIDE products in September 1974, two years before its products were actually marketed. In September 1974 Pfizer's MINIPRESS products were not yet on the market, being in the developmental stage about two years away from their commercial introduction in the United States. Accordingly, in order for Bolar's copying theory to succeed, there must be credible record evidence that Pfizer selected the trade dress for its 5 mg. and 2 mg. MINIPRESS products prior to CIBA-GEIGY's selection in September 1974, and that those responsible for the choice of APRESAZIDE's trade dress knew or had reason to know the form and colors in which the MINI-

PRESS products would ultimately be marketed. The record is barren of any such evidence.[8]

Apart from the fact that there is no proof of when Pfizer actually selected the final trade dress for its MINIPRESS products, the two CIBA-GEIGY officials responsible for the selection of APRESAZIDE's trade dress, Mr. Barnes and Mr. Marmaras, denied that they even knew in September 1974, the trade dress in which Pfizer would ultimately market MINIPRESS, much less that they copied that trade dress. There is no proof that CIBA-GEIGY had advance knowledge of the colors of Pfizer's MINIPRESS capsules as early as September 1974 or at any time before they were actually marketed.

In September 1974, CIBA-GEIGY did undertake to bring its APRESAZIDE products to the market on an "urgen[t]" basis. The urgency behind the APRESAZIDE project in 1974 was CIBA-GEIGY's concern that its leading anti-hypertensive product, SER-AP-ES, might be withdrawn from the market or lose substantial sales because of an alleged link between one of its components, reserpine, and breast cancer. But even if the urgency was to race Pfizer to the marketplace, such circumstances to not warrant a finding of deliberate copying by CIBA-GEIGY.

3. *The Market Presence of the Blue and White and Pink and White MINIPRESS Products*

Bolar also contends that the market presence of Pfizer's 5 mg. blue and white and 2 mg. pink and white MINIPRESS capsules, which started two months before

[8] Bolar has offered no plausible theory as to why CIBA-GEIGY, a brand name drug manufacturer, would have wanted to copy the trade dress of another brand name company's products even before those products had established any acceptance in the marketplace. Bolar contends that it has been deprived of discovery on this issue and that any similarity could not occur by chance. However, the court cannot substitute speculation for the uncontradicted testimony of plaintiff's witnesses.

APRESAZIDE's introduction in October 1976, precludes a finding of secondary meaning in the 25 mg./25 mg. and 50 mg./50 mg. APRESAZIDE capsules.

It is the overall appearance of MINIPRESS's trade dress that is critical for the resolution of this matter. Pfizer's 5 mg. blue and white MINIPRESS capsules are not similar in overall appearance to CIBA-GEIGY's 25 mg./25 mg. blue and white APRESAZIDE capsules. (Compare D-2 with P-2). Pfizer's blue and white capsules are noticeably larger than the CIBA-GEIGY blue and white capsules. Of course, such differences may not be readily apparent, because, as indicated above, a patient does not make a side-by-side comparison.

Insofar as the pink and white capsules are concerned, while the overall appearance of the Pfizer and the CIBA-GEIGY products are similar and while they are both antihypertensive, there is no real likelihood of patient confusion between the two. MINIPRESS contains a single active ingredient (prazosin hydrochloride) which is chemically, pharmaceutically and generically different than APRESAZIDE's two active ingredients (hydralazine hydrochloride and hydrochlorothiazide); moreover, MINIPRESS has no diuretic component while APRESAZIDE combines a thiazide diuretic with a direct-acting vasodilator. For this reason, no pharmacist could lawfully substitute MINIPRESS for APRESAZIDE, even if a physician's prescription allows substitution. Moreover, there is no reason to believe that a pharmacist would illegally substitute MINIPRESS for APRESAZIDE since they are comparable in price, thus removing the economic incentive for such conduct.

The similarity between APRESAZIDE and MINIPRESS does not preclude the trade dress of APRESAZIDE from acquiring secondary meaning. The trade dresses of APRESAZIDE and MINIPRESS products can both simultaneously achieve secondary meaning among two distinctly different groups of patients, APRESAZIDE users on the one hand, and MINIPRESS users on the other.

4. *Bolar's Claim that CIBA-GEIGY's APRESAZIDE Trademark has Become Generic or has been Abandoned*

Bolar itself has never used APRESAZIDE as the common descriptive name for its generic combinations of hydralazine hydrochloride and hydrochlorothiazide. On the contrary, Bolar has consistently recognized that hydralazine hydrochloride/hydrochlorothiazide is the common generic name for such products and has consistently used it as such. The record establishes that hydralazine hydrochloride/hydrochlorothiazide is the commonly recognized generic name of the products in suit, and that it has been "useful" enough for Bolar itself to utilize it as such. Moreover, CIBA-GEIGY itself has uniformly included hydralazine hydrochloride/hydrochlorothiazide as the established generic name for its APRESAZIDE branded products in all of its promotional literature disseminated outside of the company.

Equally unsupported is Bolar's claim of trademark abandonment by CIBA-GEIGY's alleged failure "to use the name APRESAZIDE in accordance with its corporate policy for maintenance and protection of its trademarks . . . ." The court has reviewed CIBA-GEIGY's corporate trademark protection policy as set forth in Exhibit D-4 and concludes that there is no evidence in the record which would indicate a material departure from this policy in the case of CIBA-GEIGY's APRESAZIDE trademark.

Bolar has introduced no evidence that CIBA-GEIGY either committed any acts of abandonment or had an actual intent to abandon its APRESAZIDE trademark.

G. *Bolar's Intent to Induce Illegal Substitution*

Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide products at the expense of CIBA-GEIGY's APRESAZIDE products.

Illegal substitution occurs when the physician's prescription precludes generic substitution, and yet the pharmacist, without advising the patient, nevertheless dispenses a generic equivalent and charges the same price he normally charges for the brand name counterpart. The economic incentive for such conduct is provided by the fact that generic drugs are usually less expensive to purchase at wholesale than their brand name counterparts.

The court finds that duplication of APRESAZIDE's trade dress would facilitate illegal substitution. Patients will not be alerted to illegal substitution if the generic equivalent's trade dress is identical to that of the brand name counterpart.

It is difficult to envision how legitimate substitutions would be adversely affected by a difference in appearance. Either before of after the substitution is made the patient is entitled to and would normally receive an explanation. Most would be satisfied with that explanation. There is no evidence to support rejection by patients based upon a difference in appearance after such explanation.

Why then does the defendant insist upon duplicating the appearance of plaintiff's product? There is a good likelihood that it is because Bolar recognizes that such identity facilitates illegal substitution.

By deliberately copying APRESAZIDE's trade dress, not only did Bolar have reason to anticipate the passing off of its look-alike products for CIBA-GEIGY's APRESAZIDE products, but there is a substantial likelihood that plaintiff will succeed in proving that Bolar actually intended to facilitate such illegal substitution among pharmacists in order to increase its sales. To reach any other conclusion would ignore the realities of the situation. The court recognizes that such an indictment could logically extend to any generic manufacturer who produced a look-alike drug. The facts of this case however indicate that there is a likelihood that the identity of appearance was intended, at least in part, to promote illegal not legal

substitution, since such identity is unnecessary to informed, legal substitution. Unfortunately the existence of illegal substitution has become all too prevalent.[9]

H. *Irreparable Harm and the Balance of Equities*

CIBA-GEIGY will sustain irreparable harm if preliminary injunctive relief is not granted. The balance of equities is in CIBA-GEIGY's favor.

Because illegal substitution is, by definition, undisclosed, CIBA-GEIGY will be unable to estimate accurately the full extent of its lost sales caused by Bolar's facilitation of this practice.

I. *The Public Interest*

By facilitating illegal substitution, Bolar's conduct places APRESAZIDE patients in jeopardy. Doctors have a right to demand and expect that their specific instructions shall be carried out. Defendant's look-alike drug permits the doctor's instructions to be easily thwarted. The patient

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[9] A total of 93 pharmacists and pharmacies in New York City, (27 in 1982 and 66 in 1980) have been criminally prosecuted and convicted for engaging in illegal substitution, while charges remain outstanding against another 61. The court takes judicial notice of these criminal convictions in this proceeding. *See* Fed. R. Evid. 201; *United States v. Alldredge*, 468 F.2d 684, 686 n.2 (3d Cir. 1972), *cert. denied sub nom. Martinez v. Alldredge*, 412 U.S. 920 (1973); *Ruth v. First Nat'l Bank*, 410 F. Supp. 1233, 1234 (D.N.J. 1976). While in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 102 S. Ct. 2182, 2190 n.19 (1982), the Supreme Court recently expressed skepticism about the Second Circuit's taking judicial notice of indictments which "involved no convictions" and which were "not available when the district court rendered its decision", that is plainly not the situation here. Finally, there are cases in this circuit which have documented the existence of illegal substitution. *See SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1059 (3d Cir. 1980); *Hoffman LaRoche, Inc. v. Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374, 380 (D.N.J. 1980); *Boehringer Ingerlheim G.m.b.H. v. Pharmadyne Laboratories*, 532 F Supp. 1040, 1059-60 & n.27 (D.N.J. 1980).

likewise has a right to expect that he or she will receive the exact medication prescribed. The existence of a look-alike drug deprives the patient of the sole means of learning that he or she is receiving a drug other than that prescribed. It may be unfair to the many ethical and honest pharmacists to predicate a rule of law upon an assumption that some pharmacists do and may illegally substitute generic drugs in order to make a greater profit. However, the evidence supports a finding that such practice is not uncommon and obviously may be more prevalent because of the inability to discover its extent.

Even in the case of legal substitution, Bolar's conduct endangers the public interest. If Bolar's products look confusingly similar to CIBA-GEIGY's, the patient may never learn or fully understand that they are not made by the same manufacturer as the products he had previously been taking—thereby jeopardizing his right to give his informed consent to the substitution.

A patient who has had a satisfactory experience with a drug may more readily agree to a generic substitute of the same appearance. At first blush, such conclusion may appear consistent with Bolar's arguments regarding functionality. However, such similarity may cause the patient to make the unwarranted assumption that the medication is identical and from the same manufacturer as the prior medication. In this area fraught with risks to health, no procedure should be condoned which affords to the patient anything less than all of the pertinent information and conditions which will prompt an inquiry for such information. There is no harm to the public in differentiating between the pills; there may be great harm in not.[10]

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[10] The court recognizes its obligation to review the record and make findings and conclusions independent of the proposed findings of facts and conclusions of law submitted by the parties. The court has complied with that obligation. However, the court found it extremely difficult to improve upon many of the submissions of the plaintiff in this matter, and to a large extent has adopted same

(Footnote continued on following page)

CONCLUSIONS OF LAW

On the authority of the Third Circuit's decision in *SK&F, Co. v Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), CIBA-GEIGY alleges that Bolar's intentional duplication of the trade dress of its APRESAZIDE products constitutes unfair competition under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and two independent torts under New Jersey law: (a) the tort of "unprivileged imitation"; and (b) the tort of "passing off." The court has jurisdiction over CIBA-GEIGY's Lanham Act claims under 15 U.S.C. § 1121 and 28 U.S.C. § 1331(a) and over its New Jersey unfair competition claims under 28 U.S.C. § 1338(b) and the principles of pendent jurisdiction. In order to establish its entitlement to a preliminary injunction against Bolar's conduct, CIBA-GEIGY must demonstrate a likelihood of ultimate success as to at least one of these two claims. In addition, CIBA-GEIGY must demonstrate that it is threatened with irreparable injury absent such relief; and that the balance of equities and the public interest favors such relief. Applying the following legal principles to the foregoing fact findings, the court concludes that CIBA-GEIGY has satisfied this burden.

A. *Likelihood of Ultimate Success*

Bolar contends that CIBA-GEIGY has not met its burden with respect to either "unprivileged imitation" or "passing off" because, based upon Bolar's commercial labels and capsule markings, there is no likelihood that

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[10] *continued*
into its final opinion. The court trusts that the result will be recognized as a compliment to counsel's competence and thoroughness rather than any failing on the part of the court to consider fully and fairly all matters of fact and law presented to it.

After the initial reference to APRESAZIDE® and MINIPRESS®, the court has dropped the "®" symbol for ease of typing only. No legal significance should be attributed thereto for any reason.

its generic hydralazine hydrochloride/hydrochlorothiazide combinations will be confused with CIBA-GEIGY's APRESAZIDE products. However, as recently reiterated in *Artus Corp. v. Nordic Co.*, 512 F. Supp. 1184, 1190-91 (W.D. Pa. 1981):

> The test for customer confusion is not whether the products can be differentiated when subjected to side-by-side comparison, but whether they create the same general overall impression. [citations omitted] . . . A dissimilarity in names will often prove ineffective in preventing confusion caused by the general similarity in appearance of the product.

Bolar's purported efforts to distinguish its product from plaintiff's are unsuccessful. The labels affixed by Bolar are not seen and the identification on the capsules cannot be seen. Furthermore, as noted in the court's findings of fact, on the one hand Bolar claims a readily apparent difference, and on the other hand urges that identity exists but is essential and justified.

The court concludes that neither Bolar's commercial labels nor the imprintations on its otherwise identical capsules are sufficient to prevent the likelihood of patients confusing Bolar's products with CIBA-GEIGY's. This is particularly so given the fact that most APRESAZIDE patients are over 69 years old. Here, as in *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories*, 532 F. Supp. 1040, 1046 (D.N.J. 1980), "[o]nly those with acute vision are likely to detect differences in logo, and a substantial number of [the drug's] users will not have sufficiently sharp eyesight." Having concluded that the record establishes a significant likelihood of confusion, the court next considers CIBA-GEIGY's chances of ultimate success with respect to the independent torts of unprivileged imitation and passing off.[11]

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[11] As the Third Circuit noted in *SK&F*, except for the federal law's interstate commerce requirement, "the elements of the unfair competition torts proscribed by New Jersey law and by section 43(a) of the Lanham Act are the same. . . ." 625 F.2d at 1066. And, here, the interstate commerce requirement is plainly satisfied.

1. *The Tort of Unprivileged Imitation*

As Judge Gibbons stated in *SK&F*, the elements of the tort of unprivileged imitation "are generally expressed as conjunctive requirements of secondary meaning and nonfunctionality." 625 F.2d at 1063. In *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 102 S. Ct. 2182, 2186 n.10 (1982), the Supreme Court noted that "[i]n general terms, a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article." Expanding on this notion in *SK&F*, the Third Circuit had stated:

> Proof of nonfunctionality generally requires a showing that the element of the product serves no purpose other than identification. In the case of a drug, for example, the allegedly nonfunctional element must not enhance efficacy.

625 F.2d at 1063. Subsequently, in *Keene Corp. v. Paraflex Indus., Inc.*, 653 F.2d 822, 825 (3d Cir. 1981), the Third Circuit framed the appropriate inquiry as "the extent to which the design feature is related to the utilitarian function of the product or feature."

> When the design itself is not significantly related to the utilitarian function of the product, but is merely arbitrary, then it is entitled to protection as a design trademark if it has acquired the distinctiveness necessary to achieve secondary meaning.

Id. Applying these principles to the facts of this case, the court concludes that the trade dress of each of CIBA-GEIGY's three APRESAZIDE products is nonfunctional.

In affirming the district court's nonfunctionality finding in *SK&F*, the Third Circuit emphasized that "[t]he adoption of [DYAZIDE® 's] trade dress was arbitrary, having nothing to do with the purpose or performance of the drug, or with its processing." 635 F.2d at 1064. This court has already indicated its finding that this is equally true with respect to the trade dress of APRESAZIDE. There was no medical, pharmaceutical or manufacturing reason

that required CIBA-GEIGY to make its APRESAZIDE products in capsule rather than tablet form or in the particular colored capsules it selected. Nor was there any medical, pharmaceutical or manufacturing reason which compelled Bolar to copy the dosage form of color combinations chosed by CIBA-GEIGY.

The court rejects Bolar's contention that, because the three different color combinations of APRESAZIDE capsules serve to differentiate the capsules' three different strengths, their trade dress is functional. Rejecting a similar contention in *Ideal Toy Corp. v. Plawner Toy Manufacturing Corp.*, Civil No. 81-1431 (D.N.J. Oct. 21, 1981), *aff'd*, No. 81-3119 (3d Cir. July 26, 1982), this court stated:

> In the present instance, there are certainly numerous colors that could be used on the faces of the cube to differentiate them. In fact, it is not necessary to use solid colors at all. . . . The colors, of course, do serve a function. Some distinctive marks are necessary to differentiate the faces. But given the wide variety of possible marks, the actual colors and patches used are non-functional.

Slip Op. at 4. In *Biocraft Laboratories, Inc. v. Merck & Co.*, 532 F. Supp. 1068 (D.N.J. 1980), the court rejected the precise contention advanced by Bolar here. The fact that a manufacturer uses different colors to distinguish between its own products does not make those particular colors functional as to other manufacturers. If one strength is to be distinguished from another, any number and variety of colors or combinations thereof can be used. To suggest that the very same colors must be used is to defy common sense. Reid-Provident is presently marketing hydralazine hydrochloride/hydrochlorothiazide combination capsules which use different colors or shades to differentiate the products' three strengths but which do not duplicate the three color combinations of CIBA-GEIGY's APRESAZIDE capsules.

Bolar urges a number of other bases for concluding that CIBA-GEIGY's trade dress is functional. All of these con-

tentions are predicated upon the claim that such trade dress is utilized for identification purposes. It is inconceivable that a physician or a pharmacist would prescribe a drug based upon its appearance only. Such appearance may be utilized as a secondary or incidental means of identification, but such use hardly rises to the level of functionality which would mandate or permit copying.

As previously stated, the court likewise rejects Bolar's contention that APRESAZIDE's trade dress is functional as a means for identification in poison control or overdose situations. There is no proof that APRESAZIDE is the type of drug which is likely to engender the kind of emergency room visits where such identification would become necessary. *Cf. Boehringer Ingelheim G.m.b.H.*, 532 F.Supp. at 1049. Moreover, Bolar's own expert pharmacist testified that a drug's trade dress would rarely, if ever, be relied upon as the sole means of identification in such situations because of the "plethora" of similar-appearing medications on the market. *See also SK&F, Co.*, 625 F.2d at 1060.

The court has also rejected Bolar's anxiety-functionality contention and the related contention that APRESAZIDE's trade dress is functional because patients already taking the CIBA-GEIGY products identify the drug's physical appearance with the medical condition (i.e., hypertension) for which they are prescribed, based upon the foregoing findings of fact.

Based upon the foregoing findings of fact certain conclusions are warranted:

1. Obviously if a patient has never taken a particular drug, no special reliance upon trade dress arises.

2. Therefore, the claim of functionality can only pertain in those instances where a patient has taken a particular medication over an extended period of time.

3. Assuming the medication is successful, the patient will associate this effect with the drug and recognize it as beneficial.

4. The patient will identify such medication as being associated with the illness for which it was originally prescribed.

5. The constancy of the trade dress will permit the patient to identify it with a single source, although not the particular source.

6. If a generic equivalent is recommended and accepted, the patient will be informed.

7. If the generic drug is different in appearance, the patient will be advised or understand that it is coming from a different source.

8. The patient may accept the generic drug or reject it for that very reason or any other reason.

9. If the generic drug is identical in appearance, the patient may never know that it derives from a different source.

10. The fully informed patient can easily adjust to a new color scheme.

11. The dissimilar medication affords to the physician, the pharmacist and the patient the opportunity to differentiate between the name brand and generic product and make an informed decision; the look-alike may deprive them of that opportunity.

Despite the evidentiary record on this motion, which demonstrates to the court's satisfaction that APRESAZIDE's trade dress is nonfunctional as a matter of fact, Bolar nevertheless contends that the court is precluded from so finding as a matter of law under the Supreme Court's opinion in *Ives Laboratories, Inc.* The narrow issue in *Ives* pertained to the scope of appellate review and whether the Second Circuit had correctly reversed the district court's holding that defendant's duplication of plaintiff's trade dress for its CYCLOSPASMOL® product did not amount to contributory trademark infringement in violation of § 32 of the Lanham Act, 15 U.S.C. § 1114. In addressing that issue, the Supreme Court noted that

"[w]hile the doctrine of functionality is most directly related to the question of whether a defendant has violated § 43(a) of the Lanham Act" (the statutory provision upon which CIBA-GEIGY relies here), "a finding of functionality may also be relevant to an action involving § 32" since it tends to indicate "a legitimate reason for producing an imitative product." 102 S. Ct. at 2190 n.20. In that context, the Supreme Court held in *Ives* that the Second Circuit had committed reversible error by finding a § 32 violation without first rejecting the district court's factual finding of functionality as "clearly erroneous." *Id.* The very fact that the Supreme Court's reversal rested squarely upon the Second Circuit's failure to comply with the "clearly erroneous standard" of Rule 52(a) of the Federal Rules of Civil Procedure which, by its terms, applies to "findings of fact," demonstrates that the Court was *not* ruling that drug trade dress is functional as a matter of law. The Court held that the Second Circuit could not "substitute its interpretation of the evidence for that of the trial court" without complying with Rule 52(a)'s standard. 102 S. Ct. at 2190. As Justice O'Connor stated:

> The appellate court was not entitled simply to disregard the District Court's finding of functionality. . . . If the Court of Appeals disagreed with the District Court's factual findings, it should not have dismissed them without finding them clearly erroneous.

Id. at 2190 n.20.[12] Therefore, this court concludes that *Ives* does not overrule *SK&F* with respect to the nonfunctionality of drug trade dress, as Bolar contends. Nothing in *Ives* precludes this court from evaluating the rele-

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[12] Indeed, the Supreme Court did not even view the district court's factual finding of functionality in *Ives* as dispositive of plaintiff's § 43(a) claim, in which context such a finding is admittedly "directly" relevant. Rather, because § 43(a) "prohibits a broader range of practices than does § 32," the Supreme Court remanded the case to the Second Circuit for an "independent review" of *Ives*' § 43(a) claim. *Id.* at 2190.

vant evidence and concluding that the trade dress here in issue is nonfunctional.

The second element of CIBA-GEIGY's "unprivileged imitation" claim requires proof of secondary meaning. In *Ives*, the Supreme Court observed that "[t]o establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself." 102 S. Ct. at 2186 n.11. As the Third Circuit explained in *Scott Paper Co. v. Scott's Liquid Gold, Inc.*, 589 F.2d 1225, 1228 (3d Cir. 1978):

> Secondary meaning exists when the trademark [or trade dress] is interpreted by the consuming public to be not only an identification of the product, but also a representation of the product's origin. [citations omitted]. Secondary meaning is generally established through extensive advertising which creates in the mind of consumers an association between different products bearing the same mark. This association suggests that the products originate from a single source.

In order to establish secondary meaning it is unnecessary to prove that the public identifies the products' trade dress with the name of the products' manufacturer. Indeed, such a requirement would render proof of secondary meaning virtually impossible in today's world since, as the Third Circuit has aptly recognized,

> owing to the ramifications of modern trade and international distribution of goods from the manufacturer to the jobber or importer and retailer to the consumer, the source or origin of the goods bearing a well-known trademark is seldom known to the consumer.

Family Circle, Inc. v. Family Circle Associates, Inc., 332 F.2d 534, 539 (3d Cir. 1964).

Accordingly, the law is well settled that:

> . . . to establish secondary meaning it is not necessary for the public to be aware of the name of the manufacturer which produces a product; rather, *it is sufficient if the public assumes that the product comes from a single though anonymous, source.*

Processed Plastic Co. v. Warner Communications, Inc., 675 F.2d 852, 856 (7th Cir. 1982) (emphasis added). Thus, it is no more necessary here for plaintiff to prove that APRESAZIDE patients identify those products with CIBA-GEIGY than it was for plaintiff to prove in *SK&F* that DYAZIDE® patients identified that product with SK&F.

A product is generally considered to have acquired distinctiveness and secondary meaning when its trade dress has been copied. This rule is based on the theory that one only copies something of value and would not copy the trade dress of a product if it does not afford some commercial gain. In determining whether a trademark or other symbol has acquired secondary meaning it is appropriate to consider the length and manner of its use and the nature and extent of advertising and promotions featuring the particular trade dress.

Secondary meaning can also be inferred by the court from the extensive sales of goods sold under the particular trade dress.

Applying these criteria to the facts, CIBA-GEIGY has demonstrated a strong likelihood of ultimate success on this element of its case. *See Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories*, 532 F. Supp. at 1055-56, 1063-64.

The court also rejects Bolar's contention premised upon the market presence of Pfizer's MINIPRESS capsules that CIBA-GEIGY's product is not entitled to secondary meaning. In order to acquire secondary meaning, a particular trade dress need not signify to all members of the

consuming public that the product emanates from a single, exclusive source. As the First Circuit explained in *President & Trustees of Colby College v. Colby College—New Hampshire*, 508 F.2d 804, 807 (1st Cir. 1975):

> In order to find secondary meaning the district court required proof that "the name 'Colby College' . . . exclusively signifies] the plaintiff institution in the mind of the public." [citations omitted.] Careful reading of both opinions suggests the court may have felt that exclusivity was lost if, to some persons, the name meant the wrong party. This is not so. . . . *There is sufficient secondary meaning as long as a significant quantity of the consuming public understand a name as referring exclusively to the appropriate party* . . . . (emphasis added).

Accordingly, the court concludes that the trade dress for APRESAZIDE's 25 mg./25 mg. and 50 mg./50 mg. capsules can achieve and has achieved secondary meaning among patients taking those products—the number of which is significant, despite the fact that patients taking MINIPRESS may associate the same color combinations with a different product and source. This conclusion is buttressed by the cases which have held that third-party use of a similar, if not identical trade dress or mark does not demonstrate a likelihood of confusion where, due to geographic barriers, distinct distribution channels, government regulations or the like, the probability is minimal that the consumers of plaintiff's products will ever be confronted with the third-parties' products. *See Dawn Donut Co. v. Hart's Food Stores, Inc.*, 267 F.2d 358, 364-65 (2d Cir. 1959); *National Lead Co. v. Wolfe*, 223 F.2d 195, 204 (9th Cir.) *cert. denied*, 350 U.S. 883 (1955); *David Crystal, Inc. v. Soo Valley Co.*, 471 F.2d 1245, 1246-47 (C.C.P.A. 1973); *Lever Brothers Co. v. American Bakeries Co.*, 537 F. Supp. 248, 254 (E.D.N.Y. 1982); *Central Bank & Trust Co. v. National Bank of Washington*, 187 U.S.P.Q. 651, 654 (D.D.C. 1975); *Modular Cinemas of America, Inc. v. Mini Cinemas Corp.*, 348 F. Supp. 578, 583 (S.D.N.Y. 1972). There is no real likelihood of APRESAZIDE pa-

tients ever being put in a position where they might confuse Pfizer's MINIPRESS products for their usual medication.

With specific reference to Bolar's affirmative defense of genericism, namely that the association between APRESAZIDE's trade dress and the products' trade name cannot prove secondary meaning because APRESAZIDE is a common descriptive name for the product in suit, Bolar's burden is a "heavy" one, particularly where, as here, the name under challenge is a federally registered trademark which carries a presumption of validity. *E.I. DuPont de Nemours & Co. v. Yoshida International, Inc.*, 393 F.Supp. 502, 523 (E.D.N.Y. 1975); *Coca-Cola Co. v. Pace*, 283 F. Supp. 291, 293 (W.D. Ky. 1968). In the context of CIBA-GEIGY's preliminary injunction motion, Bolar must demonstrate a probability that it will ultimately succeed at trial in carrying the burden of this affirmative defense. The court concludes that Bolar has not so demonstrated. This is particularly so in light of Bolar's own, consistent use of hydralazine hydrochloride/hydrochlorothiazide as the generic name of the product in suit, which is strong evidence that APRESAZIDE has not become the generic appellation. *See Salton Inc. v. Cornwall Corp.*, 477 F. Supp. 975, 986 (D.N.J. 1979). What more significant proof could there be than that the defendant, which is seeking to be a major competitor of the plaintiff, does not itself utilize plaintiff's brand name in a generic sense.

Bolar has similarly failed to demonstrate the requisite likelihood of ultimate success on its affirmative defense of trademark abandonment—a defense which, as the Third Circuit has recently held, "must be strictly proved." *United States Jaycees v. Philadelphia Jaycees*, 639 F.2d 134, 139 (3d Cir. 1981). Under the Lanham Act, 15 U.S.C. § 1127, a federally-registered trademark is deemed "abandoned":

> (a) When its use has been discontinued with intent not to resume. Intent not to resume may be inferred from circumstances. Nonuse for two consecutive years shall be prima facie abandonment.

(b) When any course of conduct of the registrant, including acts of omission as well as commission, causes the mark to lose its significance as an indication of origin.

Proof of abandonment under subsection (a) embodies the "twin requirement of non-use and intent to abandon." *United States Jaycees*, 639 F.2d at 138. Measured against the criteria for determining whether these twin elements have been satisfied, see *id.* at 139, the court concludes that CIBA-GEIGY has not abandoned its APRESAZIDE trademark within the meaning of subsection (a). For the same reasons, Bolar has failed to demonstrate a likelihood of ultimate success on an affirmative defense of abandonment within the meaning of subsection (b). There is no persuasive evidence of conduct by CIBA-GEIGY constituting non-use of its APRESAZIDE trademark of an intent to abandon that mark; nor is there any proof of conduct by CIBA-GEIGY which has caused its APRESAZIDE trademark to lose its significance as an indication of origin.

The court concludes that CIBA-GEIGY has established the requisite likelihood of ultimate success on the elements of nonfunctionality and secondary meaning to support the issuance of a preliminary injunction on its claim of "unprivileged imitation" under § 43(a) of the Lanham Act and New Jersey law. Having so concluded, although it is unnecessary for the court to assess CIBA-GEIGY's likelihood of ultimate success on its independent claim of "passing off," the court will proceed to address it for the sake of completeness in the event of possible appellate review.

2. *The Tort of Passing Off*

In *SK&F*, what constituted illegal "passing off" under § 43(a) of the Lanham Act and New Jersey law was the facilitation by defendant, through its intentional imitation of DYAZIDE's trade dress, of the "practice by some unscrupulous pharmacists of substituting less expensive generic drugs for the brand name drugs prescribed with-

out informing their customers and without passing along the benefit of the lower price." 625 F.2d at 1063. As the Third Circuit explained:

> [I]t has been held that it is actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form which the manufacturer *can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off.*

Id. at 1062 (emphasis added).

Accord, e.g., Hoffman LaRoche, Inc. v. Premo Pharmaceutical Laboratories, Inc., 210 U.S.P.Q. 374, 383 (D.N.J. 1980); *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories*, 538 F. Supp. at 1058-59 (D.N.J. 1980).

The court concludes that Bolar, in copying APRESAZIDE's trade dress, reasonably anticipated that its look-alike capsules would be passed off by pharmacies as CIBA-GEIGY's APRESAZIDE products to a not insignificant degree. However, Bolar argues that the Supreme Court's decision in *Ives* "overruled" *SK&F*'s "reasonable anticipation" standard for the tort of passing off under § 43(a) of the Lanham Act.

The Supreme Court's reversal in *Ives* was limited to plaintiff's claim of contributory trademark infringement under § 32 of the Lanham Act, 15 U.S.C. § 1114. Indeed, the Court remanded the case to the Second Circuit for an "independent review" of *Ives'* § 43(a) claim, because that provision "prohibits a broader range of practices than does § 32, as may the state unfair competition law. . . ." 102 S. Ct. at 2190. They key passage is contained in the concluding paragraph of Justice O'Connor's majority opinion, which reads as follows:

> **Although the District Court also dismissed Ives' claims alleging that the petitioners violated § 43(a) of the Lanham Act and the state unfair competition law, the Court of Appeals did not address those claims. Because § 43(a) prohibits a broader range of**

> practices than does § 32, as may the state unfair competition law, the District Court's decision dismissing *Ives'* claims based upon those statutes must be independently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion.

Id.

Accordingly, *Ives'* purported rejection of the "reasonable anticipation" standard was limited to § 32 claims of contributory trademark infringement, leaving unaffected, pending further review, the lower court decisions with respect to § 43(a)'s admittedly "broader" reach. Thus, *SK&F*'s "reasonable anticipation" standard for the tort of passing off under § 43(a) remains the law in this circuit.

Section 43 outlaws a broader range of practice than does § 32. Citing Judge Hastie's "leading" opinion in *L'Aiglon Apparel, Inc. v. Lang Lobell, Inc.*, 214 F.2d 649 (3d Cir. 1954), the Third Circuit in *SK&F* stated that "[i]t is well established that section 43(a) proscribes not only acts that would technically qualify as trademark infringement, but also unfair competitive practices involving actual or potential deception," including the tort of passing off. 625 F.2d at 1065. By putting in the hands of pharmacists, through intermediate wholesalers and distributors, a product which admittedly will facilitate illegal passing off, Bolar knowingly creates a real potential for deception, whether or not it is technically guilty of contributory trademark infringement.

Alternatively, even assuming that *SK&F*'s "reasonable anticipation" standard does not survive *Ives*, CIBA-GEIGY has demonstrated a likelihood of success in establishing that Bolar copied its trade dress with the intention, at least in part, to induce or permit illegal substitution. This is the higher standard for contributory infringement championed by Justice White, 102 S. Ct. at 2192 (White, J., concurring) and the one which Bolar contends the *Ives* majority in fact adopted. In the context of this motion, it is unnecessary for CIBA-GEIGY to satisfy its

ultimate burden of proving such an intent. All that is required is proof of a likelihood of ultimate success on that issue. Based upon the court's findings of fact, the court concludes that CIBA-GEIGY has made such a showing. There is a substantial lieklihood that CIBA-GEIGY will be successful in proving that although Bolar intended that its product would facilitate legal substitution, it also contemplated and intended that illegal substitution would take place as well.

In sum, applying either the "reasonable anticipation" or the actual "intent" standard, the court concludes that CIBA-GEIGY has established the requisite likelihood of success to support the issuance of a preliminary injunction on its independent claim of "passing off" under § 43(a) of the Lanham Act and New Jersey law.

B. *Irreparable Harm and the Balance of Equities*

Despite evidence of prosecution, and convictions, the extent of illegal substitution may never be known. Plaintiff's claim of irreparable injury is supported by defendant's anxiety theory. If patients will not be anxious because the generic product looks identical to the brand-name product, it is because the patient cannot and does not distinguish between them. Therefore, there would be no reason to complain since the patient will be unaware of the illegal substitution. Under such circumstances, the extent of such substitution can never be discovered, for the very reason that permitting the existence of an identical appearing product virtually destroys the ability to obtain satisfactory information.

The court concludes that it will be impossible for CIBA-GEIGY to calculate the full extent of any lost APRESAZIDE sales resulting from the illegal substitution facilitated by Bolar's conduct, since by definition such substitution will be undisclosed. This exacerbates the normally "difficult" problem of proving lost sales due to infringement.

In *SK&F*, the Third Circuit affirmed the district court's finding of threatened irreparable injury on the following ground:

> Unknowing or willful substitution [of Premo's product for DYAZIDE®] even if legally permissible would expose SKF not only to the risk of patient and physician dissatisfaction if the patient reacted to the substitute drug differently, but also to the risk of suit for the resulting consequences. In such a suit the striking similarity in appearance of the two products would make it unlikely that SKF, the deep pocket defendant, could prove that the harm was caused instead by Premo capsules, because the only proof as to the source would be the capsules long since digested by the patient.

625 F.2d at 1066.

The court is also obligated to balance the equities. It is difficult to envision what equities Bolar can assert. It knowingly copied plaintiff's product for the specific purpose of gaining an economic advantage thereby. It is or should be familiar with the law on this subject. Whatever actions it took, whatever expenses it incurred, it did so with full knowledge of the probable consequences. Its risks were known and calculated. Here, as in *SK&F*, Bolar's position "is almost totally devoid of equities." *Id.* As the court has already concluded, there was no functional reason which compelled Bolar to copy the trade dress of CIBA-GEIGY's products. Like Reid-Provident, Bolar could have begun marketing its hydralazine hydrochloride/hydrochlorothiazide combinations in March 1982 in differently colored capsules than APRESAZIDE, if not in tablet form, and achieved the same strong market position which it admits Reid-Provident has achieved.

C. *The Public Interest*

The primary basis for issuing an injunction in this matter, however, is protection of the public interest. Absent some harm or potential harm to the public, the courts

might be more inclined to permit the parties to wage these battles in the marketplace rather than in the courts. However, this case presents a typical instance in which the court's edict is necessary to protect the public which stands unrepresented in this proceeding.

Stated in its most simple form the public will be harmed by the existence of defendant's product because it permits, if not encourages, illegal substitution. As the court has already noted in its findings of fact, such a determination is not meant to be a condemnation of all pharmacists or even a large portion thereof. But the facts support a finding that the practice exists, and therefore we must deal with the realities. There are laws against turning back mileage indicators on used cars, not because all dealers do it, but because some have and will.

The court concludes that the public interest will be served by the issuance of a preliminary injunction which, in effect, will prohibit the facilitation of illegal substitution. Certainly if such illegal substitution was intended, all the more reason why injunctive relief is appropriate.

Even in the case of legal substitution, Bolar's conduct endangers the public interest by jeopardizing the consumer's admitted right to sufficient information so that he can give informed consent to such substitution. If the physician has authorized the substitution without informing the patient, the patient will never know, if the generic is identical to the brand-name product previously administered. Even under these circumstances the court does not believe that the patient should be deprived of the opportunity of recognizing that a change has taken place. The look-alike drug deprives the patient of that opportunity. That Bolar's look-alike products may be chemically and therapeutically identical to CIBA-GEIGY's APRESAZIDE products does not obviate this threat to the public's right of informed consent. For as the Supreme Court has held:

> If consumers or dealers prefer to purchase a given article because it was made by a particular manufac-

> turer or class of manufacturers, they have a right to do so, and this right cannot be satisfied by imposing upon them an exactly similar article, or one equally as good, but having a different origin.

F.T.C. v. Colgate-Palmolive Co., 380 U.S. 374, 388 (1965), *quoting F.T.C. v. Royal Milling Co.*, 288 U.S. 212, 216 (1933).

Finally, the court rejects Bolar's argument that the injunction sought by CIBA-GEIGY is "anticompetitive" in that it seeks to use the trademark laws to perpetuate an expired patent monopoly and thus stifle legitimate competition. This precise argument was made in *SK&F* and flatly rejected by the Third Circuit. *See* 625 F.2d at 1064-65, 1067.

CONCLUSION

The court holds that CIBA-GEIGY has demonstrated its right to a preliminary injunction against Bolar's duplication of the trade dress of CIBA-GEIGY's APRESAZIDE products and an order will be entered to that effect.

/s/ H. Lee Sarokin
U.S.D.J.

DATE: August 10, 1982

Original to Clerk, U. S. District Court
Copy to Counsel

Filed December 16, 1983

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant,

BOLAR PHARMACEUTICAL CO., INC.,

Counterclaim-Plaintiff,

v.

CIBA-GEIGY CORPORATION,

Counterclaim-Defendant.

* * * *

BOLAR PHARMACEUTICAL, INC.,

Plaintiff,

v.

CIBA-GEIGY, LTD.,

Defendant.

Civil Action No. 82-788
Honorable H. Lee Sarokin

ORDER ON CONSENT DISMISSING COUNTERCLAIMS AND CONSOLIDATING HEARING WITH TRIAL ON THE MERITS

This Court having held hearings on April 22, May 12 and June 15, 1982 on the motion of plaintiff Ciba-Geigy Corporation for preliminary injunction, plaintiff being satisfied with the sufficiency of its proof therein for purposes of a trial on the merits, and defendant believing it submitted sufficient evidence and made offers of proof therein to defeat plaintiff's claims at a trial on the merits, it is this 16 day of December, 1983,

ORDERED upon consent and stipulation of the parties that

(1) Each of the supplemental and amended counterclaims in this action, whether asserted against plaintiff or Ciba-Geigy, Ltd., and the claims for relief set forth in the Complaint under §32 of the Lanham Act, 15 U.S.C. §1114, are dismissed without prejudice and without costs or attorneys fees to any party.

(2) The hearings held on April 22, May 12, and June 15, 1982 on plaintiff's motion for preliminary injunction shall constitute the trial on the merits in this action.

/s/ H. Lee Sarokin
U.S.D.J.

The parties hereto, by their duly authorized attorneys, hereby consent to the entry of the above order.

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Filed December 23, 1983

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant.

Honorable H. Lee Sarokin
Civil Action No. 82-788

FINAL JUDGMENT AND ORDER

This Court having held hearings in this action on April 22, May 12, and June 15, 1982 on plaintiff's motion for preliminary injunction; the Court having heard and considered the evidence, offers of proof and arguments of counsel; the Court having filed its opinion on August 11, 1982 granting plaintiff's motion for preliminary injunction and having issued a preliminary injunction on October 4, 1982; the Court of Appeals for the Third Circuit having affirmed the grant of the preliminary injunction on October 14, 1983; the parties having consented to converting the hearings held on plaintiff's motion for preliminary injunction to the final trial on the merits; and the Court having concluded that on the present record and for the reasons set forth in its opinion of August 11, 1982, CIBA-GEIGY is entitled to final relief;

It is on this 22 day of December, 1983, ORDERED, ADJUDGED AND DECREED

A. That the preliminary injunction issued on October 4, 1982 is made permanent;

B. That judgment is entered in favor of plaintiff and against defendant on the claims for relief set forth in the Complaint under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), New Jersey statutes Annotated Sections 56:4-1 and 56:8-2 and the common law of unfair competition of the State of New Jersey; and

C. That except for the judgment of this Court dated August 24, 1983 awarding fees and costs of $12,500.00 to plaintiff, each party shall bear its own costs and attorneys fees, and no party shall be awarded monetary damages.

/s/ H. Lee Sarokin, U.S.D.J.

We hereby approve the
form of this Order

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Attorneys for Bolar Pharmaceutical Co., Inc.

By /s/ James F. Keegan
A Member of the Firm

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Attorneys for Ciba-Geigy Corporation

By /s/ Frederick L. Whitmer
A Member of the Firm

FEDERAL STATUTE INVOLVED

Section 43(a) of the Lanham Act
15 U.S.C. § 1125(a)

§ 1125. False designations of origin; false description or representation

(a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

NEW JERSEY STATUTES

ARTICLE 1. GENERAL PROVISIONS

56:4-1. Appropriation of name, brand, trade-mark, reputation or goodwill of maker by dealer in product of maker

No merchant, firm or corporation shall appropriate for his or their own use a name, brand, trade-mark, reputation or goodwill of any maker in whose product such merchant, firm or corporation deals.

56:8-2. Fraud, etc., in connection with sale or advertisement of merchandise or real estate as unlawful practice

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice; provided, however, that nothing herein contained shall apply to the owner or publisher of newspapers, magazines, publications or printed matter wherein such advertisement appears, or to the owner or operator of a radio or television station which disseminates such advertisement when the owner, publisher, or operator has no knowledge of the intent, design or purpose of the advertiser.

Filed July 7, 1982

UNITED STATES COURT OF APPEALS
SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals in and for the Second Circuit, held at the United States Courthouse in the City of New York on the seventh day of July, One Thousand Nine Hundred and Eighty-Two.

Present: HONORABLE J. EDWARD LUMBARD,
HONORABLE WALTER R. MANSFIELD,
Circuit Judges.

IVES LABORATORIES, INC.,

Plaintiff-Appellant,

Dkt. No. 80-7314 -against-

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL, INC.,

Defendants-Appellees.

Ives Laboratories, Inc. ("Ives") has moved for a stay of the mandate of this court issued pursuant to the decision of the United States Supreme Court filed June 1, 1982, reversing our judgment dated January 8, 1981. We had reversed a judgment of the Eastern District of New York, Nickerson, *J.*, dismissing the complaint which alleged that the defendants' manufacture and distribution of a generic drug identical in appearance to Ives' trademarked drug CYCLOSPASMOL violated its rights under §§32 and 43(a)

of the Lanham Act, 15 U.S.C. §§1114 and 1125(a), and New York unfair competition laws. Since we based our decision upon §32 of the Act the Supreme Court, in reversing and remanding the case, directed us to review the other claims, stating:

> "Although the District Court also dismissed Ives' claims alleging that the petitioners violated §43(a) of the Lanham Act and the state unfair competition law, the Court of Appeals did not address those claims. Because §43(a) prohibits a broader range of practices than does §32, as may the state unfair competition law, the District Court's decision dismissing Ives' claims based upon those statutes must be independently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion." 50 U.S.L.W. 4592, 4596 (Sup. Ct. June 1, 1982).

The other claims were fully briefed and argued upon the appeal leading to our January 8, 1981, decision, and have been considered. Further briefing and argument is therefore unnecessary.

We affirm the judgment of the district court dismissing the other claims, substantially for the reasons stated by Judge Nickerson in his April 15, 1980, decision, which is predicated upon his findings that the color and shape of defendants' generic cyclandelate look-alike capsules serve functional purposes (e.g., therapeutic effect and identification) and that Ives' trademarked capsules had not acquired a secondary meaning creating the likelihood that it might be perceived as the source of the product. See *American Footwear Corp. v. General Footwear Co.*, 609 F.2d 655, 664 (2d Cir. 1979). We cannot label these findings clearly erroneous. See *Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc.*, ... U.S. ....., 50 U.S.L.W. at 4596 n.20. For the same reasons the dismissal of the state law unfair competition claims must stand.

Accordingly the judgment of the district court is affirmed and the motion to stay the mandate is denied.

/s/ J. Edward Lumbard
U.S.C.J.

/s/ Walter R. Mansfield
U.S.C.J.

N.B. Since this statement does not constitute a formal opinion of this court and is not uniformly available to all parties, it shall not be reported, cited or otherwise used in unrelated cases before this or any other Court.

No. 83-1163

Office - Supreme Court, U.S.
FILED
FEB 15 1984
ALEXANDER L. STEVAS,
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

—v.—

CIBA-GEIGY CORPORATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. Does the instant Petition present a justiciable controversy for this Court: (a) where the judgment of the Court of Appeals sought to be reviewed merely affirmed the grant of a *preliminary* injunction which is no longer in effect, the District Court thereafter having entered a *final* judgment *permanently* enjoining petitioner's conduct; and (b) where that final judgment has been appealed to the Court of Appeals and that court has not yet passed upon its propriety?

2. Even assuming the existence of a justiciable controversy, does this case warrant the sparing exercise of this Court's extraordinary certiorari jurisdiction: (a) where the preliminary injunction affirmed by the Court of Appeals was supported by two *alternative* findings of liability—the tort of "unprivileged imitation" and the tort of "passing off"; and (b) where, contrary to petitioner's assertion, neither finding is in conflict with this Court's decision in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) ("*Ives*"), because:

—With respect to the tort of "unprivileged imitation":

(a) The Court of Appeals *affirmed* the trial court's *factual* finding of "nonfunctionality" as not clearly erroneous, whereas in *Ives*, in the context of a claim of contributory trademark infringement, the Second Circuit *reversed* the trial court's *factual* finding of "functionality" *without* applying the clearly erroneous test; and

(b) The Court of Appeals affirmed the trial court's *factual* finding of "secondary meaning" as not being clearly erroneous, whereas in *Ives* this Court did not address the sufficiency of the evidence necessary to establish "secondary meaning"; and

—With respect to the alternative finding of "passing off":

(a) The Court of Appeals explicitly did "not address" the alleged conflict between the District Court's application of the "reasonable anticipation" standard for the tort of "passing off" under § 43(a) of the Lanham Act and *Ives*' rejection of that test for contributory infringement under § 32 of the Lanham Act, the Third Circuit instead holding that the "reasonable anticipation" standard was the appropriate test for "passing off" under New Jersey state law;

(b) *Ives* dealt only with the propriety of the "reasonable anticipation" standard for a claim of contributory infringement under § 32 of the Lanham Act and *not* for a claim of "passing off" under § 43(a) of the Act, which this Court noted in *Ives* "prohibits a broader range of practices than § 32"; and

(c) The District Court "alternatively" found that there was "a substantial likelihood that plaintiff will succeed in proving that [petitioner] *actually intended* to facilitate . . . illegal substitution among pharmacists"—a factual finding which is not clearly erroneous and which would satisfy even *Ives*' standard for contributory infringement under § 32?

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STATEMENT PURSUANT TO SUPREME COURT RULE 28.1

CIBA-GEIGY Corporation, a privately-owned New York corporation, states that its parent is CIBA-GEIGY Ltd., a Swiss corporation. Each company's subsidiaries are wholly owned.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-1163

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

—v.—

CIBA-GEIGY CORPORATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

Respondent CIBA-GEIGY Corporation ("CIBA") respectfully submits that the instant Petition fails to present a single "special and important" reason warranting the issuance of a writ of certiorari. *See* Sup. Ct. Rule 17. Indeed, the Petition does not even present a justiciable controversy for this Court. That is because the Court of Appeals' judgment sought to be reviewed merely affirmed a *preliminary* injunction—a preliminary injunction which was subsequently superseded by the District Court's entry of a *final* judgment whose propriety is presently pending on appeal to the Third Circuit. For this reason alone, it would be improvident to grant certiorari.

What is more, even assuming the existence of a justiciable controversy in this Court, the lack of any conflict between the decision below and any decision of this Court or any other

circuit court, and the numerous alternative federal and state grounds to support the District Court's decision—all of which were predicated on factual findings not deemed clearly erroneous by the Court of Appeals—lead ineluctably to the conclusion that the Petition presents no basis for the invocation of this Court's extraordinary certiorari jurisdiction.

STATEMENT OF THE CASE

The Petition presents an incomplete, misleading and distorted version of both the relevant facts and the proceedings below—not the least of which is its studied effort to bury the fact that there is no justiciable controversy before this Court because the preliminary injunction that it seeks to vacate has been superseded by a final judgment whose propriety the Court of Appeals has not yet addressed.[1]

The salient evidentiary facts are set forth in what the Court of Appeals described as the "thoughtful and detailed opinion" of the District Court (A. 4), and will not be repeated here except insofar as necessary to a proper understanding of the rulings below.[2] Suffice it to say that the Petition presents a one-sided statement of the facts, which largely ignores the District Court's findings and the substantial record evidence on which they were predicated.[3]

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1 The Petition's sole acknowledgement of this circumstance is its passing reference at page 1 to "[t]he unreported orders of the District Court converting the preliminary injunction hearing to a final trial on the merits and entering a permanent injunction. . . ." (Petition at 1) Thereafter, petitioner scrupulously avoids mentioning this fact, much less discussing its dispositive significance.

2 The District Court's opinion granting CIBA's motion for a preliminary injunction is officially reported at 547 F. Supp. 1095, and the Court of Appeals' affirmance is officially reported at 719 F.2d 56.

3 Similarly, the *amicus* briefs of the National Association of Pharmaceutical Manufacturers ("NAPM"), the American Association of Retired Persons, the National Council of Senior Citizens and the Illinois Pharmacists Association—apart from their failure to address the Petition's fatal lack of justiciability—are replete with factual state-

A. The Preliminary Injunction Proceedings in the District Court

CIBA commenced this action on March 12, 1982, alleging that petitioner Bolar Pharmaceutical Co., Inc. ("Bolar") had violated both the federal and New Jersey state law of unfair competition by intentionally duplicating the trade dress of CIBA's brand name prescription drug APRESAZIDE.[4] On March 17, 1982, the District Court temporarily restrained Bolar from selling its generic version of CIBA's product in confusingly similar trade dress and ordered Bolar to show cause why such conduct should not be preliminarily enjoined. (A. 10)

After a three-day evidentiary hearing at which seven witnesses testified and 162 exhibits were admitted into evidence (A. 11), the District Court granted CIBA's motion for a preliminary injunction. The reasons for the injunction's issuance were thoroughly set forth in a 41-page opinion which constituted the District Court's findings of fact and conclusions of law. (A. 9-50) As the trial judge took pains to note, those findings and conclusions were:

> ". . . based upon a careful review of the entire record, an appraisal of the witnesses' credibility and demeanor and the reasonable inferences to be drawn therefrom. . . ." (A. 11)

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ments and assumptions which are not only outside of, but contrary to the record underlying the District Court's fact findings. As this Court recently noted, "[t]he stated desires of *amici* concerning the outcome of this or any litigation . . . are not evidence in this case, and do not influence our decisions. . . ." Sony Corp. v. Universal City Studios, Inc., 52 U.S.L.W. 4090, 4094 n.16 (U.S. Jan. 17, 1984).

4 The term "trade dress" is used here, as it was by the courts below, in its "modern sense" to refer to the physical appearance of CIBA's APRESAZIDE products. *See* Ideal Toy Corp. v. Plawner Toy Mfg. Corp., 685 F.2d 78, 80 n.2 (3d Cir. 1982). "APRESAZIDE," a federally registered trademark, is CIBA's brand name for its antihypertensive combination products containing the drugs hydralazine hydrochloride and hydrochlorothiazide.

Applying the traditional criteria governing the issuance of a preliminary injunction, the District Court held that there was a reasonable likelihood that CIBA would establish at trial that Bolar's intentional duplication of APRESAZIDE's trade dress constituted two independent violations of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the New Jersey law of unfair competition—the separate torts of "unprivileged imitation" and "passing off." (A. 35-44, 44-47)

The District Court first addressed the two elements of "unprivileged imitation" under § 43(a) of the Lanham Act and New Jersey law—nonfunctionality and secondary meaning.[5] With respect to the former, the trial judge held that this Court's "narrow" ruling in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) ("*Ives*"), did not preclude it as a matter of law "from evaluating the relevant evidence and concluding that the trade dress here in issue is nonfunctional." (A. 39-40) And based upon that evidence, the District Court found that the adoption of APRESAZIDE's trade dress "ha[d] nothing to do with the purpose or performance of the drug, or with its processing" and that there was "no medical, pharmaceutical or manufacturing reason" that had either required CIBA to select the trade dress or had compelled Bolar to copy it. (A. 19-20, 35-36)[6]

In finding that APRESAZIDE's trade dress was nonfunctional, the Court also rejected, on the facts before it, each of

5 Consistent with prior precedent, the trial judge noted that, "except for the federal law's interstate commerce requirement"—which was plainly satisfied—" 'the elements of the unfair competition torts proscribed by New Jersey law and by section 43(a) of the Lanham Act are the same. . . .' " (A. 34 n.11)

6 In support of this conclusion, the Court found, among other things, that another pharmaceutical manufacturer "has been successfully marketing" distinctly different colored capsules "as generic alternatives" to APRESAZIDE; that the Food and Drug Administration has "declined to ***require***" that generic equivalents be sold in the same trade dress as their brand name counterparts; and that the New Jersey Drug Formulary has taken the "official position" that "differences [in appearance] do ***not*** affect how well the medication works." (A. 20-21; emphasis in original)

Bolar's functionality arguments, the "principal" one being that "patients with chronic illnesses such as hypertension identify the trade dress of their medications with the medical condition for which they are prescribed and that, accordingly, it is necessary for generic equivalents to duplicate the physical appearance of their brand name counterparts to prevent patient confusion and anxiety unless illegal substitution occurs." (A. 21) Based on the testimony of Bolar's own medical expert, the District Court found that any "fears or anxieties of the patient" caused by a different-appearing generic equivalent are "invariably" allayed by an explanation from his physician or pharmacist—which is "standard medical and pharmacy practice"—and that any "temporary anxiety is immediately dissipated." (A. 22, 37-38)

Turning to the second element of "unprivileged imitation," the District Court applied the "well-settled legal criteria for determining secondary meaning" to the record facts, and held that CIBA had demonstrated "a strong likelihood of ultimate success" on this issue as well. (A. 24)[7] In brief, the Court based this finding on:

> "(a) the extended, continuous and exclusive use by CIBA-GEIGY of APRESAZIDE's trade dress; (b) the extensive and costly activities of CIBA-GEIGY in promoting its APRESAZIDE products and their distinctive and arbitrary trade dress; (c) the commercial success that CIBA-GEIGY's APRESAZIDE products have achieved in the market place; and (d) Bolar's intentional copying of APRESAZIDE's trade dress. . . ." (*Id.*)

With specific reference to the last factor, the District Court found that "Bolar deliberately copied the trade dress of CIBA-

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7 In discussing the "well-settled" legal criteria for determining secondary meaning (A. 40-41), the trial judge expressly took account of this Court's *dictum* in *Ives* that "[t]o establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself." (456 U.S. at 851 n.11)

GEIGY's APRESAZIDE capsules for its own economic advantage" and that "Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide combinations at the expense of CIBA-GEIGY's APRESAZIDE products." (A. 18)[8]

As an *alternative* basis for its preliminary injunction ruling, the District Court also held that CIBA had demonstrated the requisite likelihood of success with respect to the separate tort of "passing off" under both § 43(a) of the Lanham Act and New Jersey law. (A. 44-47) In particular, based upon (1) the likelihood of confusion between APRESAZIDE and Bolar's look-alike capsules; (2) the "economic incentive" for pharmacists illegally to substitute Bolar's products for CIBA's; (3) the "all too prevalent" existence of illegal substitution by pharmacists;[9] and (4) the fact that "Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its [generic equivalents] at the expense of CIBA's APRESAZIDE products," the trial judge found that Bolar's

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8 In holding in CIBA's favor on secondary meaning, the Court also rejected as without evidentiary support Bolar's contentions that CIBA itself had copied the trade dress of another brand name company's product, MINIPRESS, and that the mere market presence of that other product precluded a finding that APRESAZIDE had acquired secondary meaning among APRESAZIDE users. (A. 26-28, 41-42) Similarly, the Court found no probative evidence that "APRESAZIDE" had become the generic name of the products in suit, thereby rejecting Bolar's contention that patients' association of the APRESAZIDE brand name with the products' trade dress could not support a finding of secondary meaning. (A. 29, 43) On the contrary, the trial judge found that "[t]he record established that hydralazine hydrochloride/hydrochlorothiazide is the commonly recognized generic name of the products in suit" and that Bolar had "consistent[ly] used it as such." (A. 29)

9 In support of this conclusion, the Court took judicial notice of the fact that 93 pharmacists and pharmacies in New York City were recently *convicted* of engaging in illegal substitution, and that criminal charges remained outstanding against another 61. (A. 31 n.9)

"duplication of APRESAZIDE's trade dress would facilitate illegal substitution" and that Bolar "reasonably anticipated that its look-alike capsules would be passed off by pharmacies as CIBA's APRESAZIDE products to a not insignificant degree." (A. 29-30, 31, 47) On this basis, the Court concluded that CIBA was likely to prevail at trial on its claim of "passing off" under § 43(a), holding that the Third Circuit's "reasonable anticipation" standard for that tort[10] was unaffected by this Court's limited disposition in *Ives*. (A. 45-46) Moreover, even assuming that *Ives* had been a "passing off" case under § 43(a)—which it was not—the District Court went on to find "alternatively" that "there is a substantial likelihood that plaintiff will succeed in proving that Bolar *actually intended* to facilitate . . . illegal substitution among pharmacists in order to increase its sales"; and that, accordingly, CIBA had satisfied even *Ives*' standard. (A. 30-31, 46-47; emphasis added)

On the issue of irreparable harm, the Court concluded that "it will be impossible for CIBA-GEIGY to calculate the full extent of any lost APRESAZIDE sales resulting from the illegal substitution facilitated by Bolar's conduct, since by definition such substitution will be undisclosed"—thereby "exacerbat[ing] the normally 'difficult' problem of proving lost sales due to infringement." (A. 47) Similarly, the Court concluded that "[t]he balance of equities is in CIBA-GEIGY's favor." (A. 31)

Finally, the District Court turned to the "protection of the public interest." (A. 48) Noting that "the public will be harmed by the existence of defendant's [look-alike] product because it permits, if not encourages, illegal substitution," the trial judge concluded that "the public interest will be served by the issuance of a preliminary injunction which, in effect, will prohibit the facilitation of illegal substitution." (A. 49) And if Bolar actually intended such facilitation—which the Court

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10 *See* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1062-63 (3d Cir. 1980).

found that CIBA had a substantial likelihood of ultimately proving—"all the more reason why injunctive relief is appropriate." (*Id.*) Moreover, the Court concluded, "[e]ven in the case of legal substitution, Bolar's conduct endangers the public interest by jeopardizing the consumer's admitted right to sufficient information so that he can give informed consent to such substitution." (*Id.*)

On the foregoing basis, the District Court entered an order on October 4, 1982 preliminarily enjoining Bolar "pending final adjudication" from "using any simulation, imitation or substantial duplication of [CIBA's] distinctive trade dress . . . in connection with . . . [Bolar's] hydralazine hydrochloride/hydrochlorothiazide products for the treatment of hypertension." (A. 6) Without seeking a stay of that injunction, Bolar then appealed to the Third Circuit.[11]

B. The Court of Appeals' Affirmance

On October 14, 1983, the Third Circuit, in a *per curiam* opinion, unanimously "affirm[ed] the district court's grant of a preliminary injunction" under the "narrow scope" of appellate review traditionally applied in such cases. (A. 3-4)[12] Noting the "heavy burden" that Bolar carried in order to achieve reversal, the Court of Appeals found "no merit to [its] arguments seeking to overturn the grant of a preliminary injunction." (*Id.*) As the Third Circuit concluded:

> "After reviewing the record, the briefs and arguments of the parties, and Judge Sarokin's thoughtful and detailed opinion, we hold that the district court did not abuse its discretion, commit an obvious error in applying the law,

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11 In the Third Circuit, as in this Court, the NAPM—a trade association of generic drug manufacturers and distributors—appeared as *amicus curiae* on Bolar's behalf. The other *amici* in this Court did not feel sufficiently impelled to submit briefs in the Third Circuit.

12 The Third Circuit panel consisted of Judges Higginbotham and Hunter and, sitting by designation, Judge Giles from the Eastern District of Pennsylvania.

or make a serious mistake in considering the proof." (A. 4)

As for Bolar's contention that the district judge had erred in failing to read *Ives* as overruling the "reasonable anticipation" standard for the tort of "passing off" under § 43(a), the Third Circuit noted in a footnote that "we need not address this issue" because that standard was nevertheless "mandated" under New Jersey law; and because, in any event, under both § 43(a) and state law, the District Court's alternative holding with respect to "unprivileged imitation" provided "a sufficient independent basis for affirming the district court's grant of preliminary injunctive relief." (A. 4 n.1)

C. The District Court's Subsequent Entry of Final Judgment and Bolar's Pending Appeal From That Judgment

In December 1983—more than three weeks *before* Bolar filed its Petition seeking review of the Third Circuit's judgment affirming the issuance of the preliminary injunction—the District Court, at Bolar's urging and with CIBA's consent, converted the preliminary injunction hearings to "the trial on the merits of this action" and entered a *final* judgment which provided, *inter alia,* that "the preliminary injunction issued on October 4, 1982 is made permanent." (A. 52, 54-55) Moreover, on January 19, 1984—one week *after* it filed its Petition in this Court—Bolar appealed the District Court's final judgment to the Third Circuit—an appeal which has neither been briefed nor argued, much less decided by that court.[13]

The net effect of these developments is plain: By its Petition, Bolar is asking this Court to adjudicate the propriety of a preliminary injunction which, although affirmed by the Third Circuit, is no longer in effect, while the propriety of the final judgment, under which Bolar is now permanently restrained, is pending review by the Third Circuit.

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13 Bolar's notice of appeal is appended hereto as an addendum.

REASONS FOR DENYING THE WRIT

I. There Is No Justiciable Controversy Before This Court.

According to its statement of "jurisdiction," Bolar is seeking "[a] writ of certiorari . . . to review the judgment of the United States Court of Appeals for the Third Circuit dated and entered October 14, 1983." (Petition at 2) As already noted, that judgment did no more than "affirm the district court's grant of a preliminary injunction" (A. 4)—a preliminary injunction which has since been superseded by the District Court's entry of a *final* judgment which is now on appeal to the Third Circuit and whose propriety has not yet been passed upon by that Court.[14]

In these circumstances, there is no justiciable controversy before this Court. Nor will there be such a controversy until the Third Circuit determines Bolar's pending appeal from the District Court's final judgment and the unsuccessful party seeks a writ of certiorari from this Court to review that determination. Since the judgment of the Third Circuit which Bolar is presently seeking to review merely affirmed, under the Third Circuit's "narrow scope of review," the issuance of a preliminary injunction which is no longer in effect, what Bolar actually seeks from this Court is an opinion on the propriety of the District Court's subsequently entered permanent injunction *before* that issue has been addressed by the Third Circuit in Bolar's pending appeal to that court. For this Court to indulge Bolar would run directly counter to its limited Article III

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14 Unquestionably, the District Court had jurisdiction to enter a final judgment despite the fact that the Third Circuit had stayed its mandate with respect to the preliminary injunction affirmance pending the filing of Bolar's present Petition. For it is well-settled that "an appeal from an interlocutory order granting or denying preliminary injunctive relief does not strip the district court of jurisdiction to proceed with the action on the merits." Thomas v. Board of Educ., 607 F.2d 1043, 1047 n.7 (2d Cir. 1979). *Accord, Ex parte* Enameling & Stamping Co., 201 U.S. 156, 162 (1906).

jurisdiction to decide only actual "cases and controversies" and its long-standing corollary rule against advisory opinions.[15]

Put another way, the District Court's entry of final judgment has rendered Bolar's Petition moot, since the Third Circuit's judgment which Bolar seeks to review was limited to the propriety of the District Court's preliminary injunction and since Bolar is no longer restrained by that temporary order but rather by a permanent injunction whose propriety has not yet been determined by an intermediate appellate court. "There being no subject matter upon which the judgment of this Court can operate, the cause is moot." *Amalgamated Association of Street, Electric Railway & Motor Coach Employees* v. *Wisconsin Employment Relations Board*, 340 U.S. 416, 418 (1957).[16]

Nor can the lack of a justiciable controversy be remedied by simply *assuming* that the Third Circuit will affirm the District Court's permanent injunction on the same basis that it affirmed the preliminary injunction. For as this Court has recently emphasized, there are "significant procedural differences between preliminary and permanent injunctions," *University of Texas* v. *Camenisch*, 451 U.S. 390, 394 (1981)—not the least of which is that a party "is not required to prove

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15 *See, e.g.*, Flast v. Cohen, 392 U.S. 83, 96 n.14 (1968); United States v. Fruehauf, 365 U.S. 146, 157 (1961); Oil Workers Unions v. Missouri, 361 U.S. 363, 367-68 (1960); Amalgamated Ass'n of Street, Elec. Ry. & Motor Coach Employees v. Wisconsin Employment Relations Bd., 340 U.S. 416, 418 (1957).

16 Application of the mootness doctrine—which, like the rule against advisory opinions, is part and parcel of the concept of justiciability and Article III's case-and-controversy limitation, *see* Flast v. Cohen, *supra*, 392 U.S. at 95—is not confined to instances where subsequent developments moot the entire lawsuit. *See* University of Texas v. Camenisch, 451 U.S. 390, 394 (1981). The present situation "is simply another instance in which one issue in a case"—here, the propriety of the District Court's preliminary injunction—"has become moot, but the case as a whole remains alive because other issues have not become moot." (*Id.*)

[its] case in full at a preliminary injunction hearing," but can prevail by demonstrating a "likelihood of success"; whereas, to obtain a permanent injunction, a party must fully establish the merits of its claims by a preponderance of the credible evidence. (*Id.* at 394, 396) And this "significant" difference leads, in turn, to a more limited standard of appellate review for preliminary injunctions than for permanent injunctions. This Court recently underscored that difference in *New York State Liquor Authority* v. *Bellanca*, 452 U.S. 714, 716 (1981):

> "[B]ecause *Doran* arose in the context of a preliminary injunction, we limited our standard of review to whether the District Court abused its discretion in concluding that plaintiffs were *likely* to prevail on the merits of their claim, not whether the ordinance actually violated the First Amendment. *Thus, the decision may not be considered a 'final judicial decision based on the actual merits of the controversy.*' " (Emphasis added)[17]

For this reason, the normal appellate process cannot be circumvented by treating the Third Circuit's affirmance of the District Court's preliminary injunction as its yet-to-be-rendered decision on the actual merits of the controversy and the propriety of the District Court's final judgment. It is beside the point that the final judgment is predicated on precisely the same record as the preliminary injunction order. (A. 54) The critical fact is that the District Court's conversion of the preliminary injunction proceedings to the trial of the merits occurred *after* the Third Circuit's affirmance under its "narrow scope of review." Thus, until that court passes upon the merits of Bolar's pending appeal, it is impossible to know

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17 Accordingly, this Court has long held that, absent "exceptional" circumstances, it will "not issue a writ of *certiorari* to review a decree of the Circuit Court of Appeals on appeal from an interlocutory order." American Constr. Co. v. Jacksonville Ry., 148 U.S. 372, 384 (1893). *A fortiori*, certiorari should be denied where the interlocutory order appealed from has been superseded by a final judgment which is pending review by the Court of Appeals.

whether it will reach the same result exercising plenary review. Although CIBA is firmly convinced that it will again prevail on appeal, neither the strength of that conviction nor Bolar's willingness to concede the outcome is a substitute for an authoritative ruling from the Court of Appeals affirming the District Court's final judgment. For as this Court has repeatedly held, "[n]o stipulation of parties or counsel . . . can enlarge the power, or affect the duty of the court" not to render "advance expressions of legal judgment upon issues which remain unfocused because they are not pressed before the Court with that clear concreteness provided when a question emerges precisely formed and necessary for decision. . . ." *United States* v. *Alaska Steamship Co.*, 253 U.S. 113, 116 (1920); *United States* v. *Fruehauf, supra*, 365 U.S. at 157.

In sum, the present Petition fails to present a justiciable controversy for this Court to resolve and, for that reason alone, certiorari should be denied.

II. Even Assuming the Existence of a Justiciable Controversy, This Case Does Not Warrant the Exercise of This Court's Extraordinary Certiorari Jurisdiction.

A. The Lower Courts' Finding With Respect to the Tort of "Unprivileged Imitation" Presents No Conflict With This Court's Narrow Disposition in *Ives*.

As previously noted, the District Court found that CIBA was likely to prove at trial that Bolar's intentional copying of APRESAZIDE's trade dress constituted "unprivileged imitation" in violation of both § 43(a) of the Lanham Act and state unfair competition law (A. 35-44); and the Third Circuit affirmed that finding as "a sufficient independent basis" to support the District Court's preliminary injunction. (A. 4 n.1) Contrary to Bolar's contention (Petition at 15-26), these rulings do not "conflict" with this Court's limited disposition in *Ives*—either with respect to "nonfunctionality" or "secondary meaning," the two constituent elements of "unprivileged imitation."

Insofar as nonfunctionality is concerned, the difference in result between this case and *Ives* is attributable not to any conflict in legal standards, but solely to the fact that two trial judges, after evaluating the credibility of the witnesses and weighing the evidence before them, reached different factual conclusions with respect to the issue—hardly a matter which is worthy of certiorari. As for secondary meaning, this Court did not even address the issue in *Ives*, except in a passing footnote which the trial judge here expressly took into account in finding, on the record before him, that CIBA was likely to prevail on that element of "unprivileged imitation" as well—another fact-bound determination which does not warrant certiorari.

1. *Nonfunctionality*

Contrary to Bolar's contention, the District Court did not "specifically decline[ ] to follow the legal standards for 'functionality' . . . affirmed by this Court in [*Ives*]." (Petition at 3) In fact, the trial judge quoted precisely the legal standard for functionality enunciated by this Court in *Ives* and, applying that standard to the evidence before him, found as a matter of fact that APRESAZIDE's trade dress was nonfunctional. (*See* A. 35, *quoting* 456 U.S. at 850 n.10) Thus, in order to manufacture a conflict, Bolar is forced to argue that *Ives* holds *as a matter of law* that the trade dress of every prescription drug product is functional. (Petition at 17-19) As the District Court correctly held, this sweeping contention fundamentally misconceives *Ives*' limited holding.

The narrow issue resolved by this Court in *Ives* was whether the Second Circuit had exceeded the scope of its appellate review by reversing the trial court's holding that the defendants' duplication of the plaintiff's trade dress for its CYCLOSPASMOL product did not constitute contributory trademark infringement in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114. While the district court in *Ives* had also rejected plaintiff's § 43(a) claim on the facts before it,

neither the Second Circuit nor this Court reached that holding. (456 U.S. at 853, 858-59)[18]

In deciding the § 32 issue in *Ives*, this Court noted that "[w]hile the doctrine of functionality is most directly related to the question of whether a defendant has violated § 43(a) of the Lanham Act"—the statutory provision relied upon here—"a finding of functionality may also be relevant to an action involving § 32," since it tends to indicate "a legitimate reason for producing an imitative product." (456 U.S. at 858 n.20) In that limited context, this Court held that the Second Circuit had committed reversible error by "substitut[ing] its interpretation of the evidence for that of the trial court" without first rejecting the District Court's fact finding of functionality as "clearly erroneous" under Rule 52(a). (*Id.* at 855, 857) As the Court explained:

> "The appellate court was not entitled simply to disregard the District Court's finding of functionality. . . . If the Court of Appeals disagreed with the District Court's factual findings, it should not have dismissed them without finding them clearly erroneous." (*Id.* at 858 n.20)

This Court's precise holding—that "[t]he Court of Appeals erred in setting aside *findings of fact* that were not clearly erroneous" (*id.* at 858; emphasis added)—puts the lie to Bolar's contention that *Ives* ruled that all drug trade dress is functional as a matter of law.[19]

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18 Thus the passage from this Court's opinion which Bolar cites as an "affirm[ance]" of the "specific tests of functionality for drug product appearance established by the trial court" (Petition at 17) is, in fact, nothing more than this Court's background recitation of what the trial court had held with respect to plaintiff's § 43(a) claim—a claim which Justice O'Connor immediately went on to state was "not reach[ed]" by the Second Circuit. (456 U.S. at 853)

19 Indeed, this Court did not even view the trial court's factual finding of functionality in *Ives* as dispositive of plaintiff's § 43(a) claim. Instead, it remanded the case to the Second Circuit for an "indepen-

The critical distinction between this case and *Ives* is that here the Third Circuit *affirmed* a district court fact finding of nonfunctionality as not being clearly erroneous, whereas in *Ives* the Second Circuit *reversed* a fact finding of functionality without holding it clearly erroneous. Thus, the District Court correctly held that "[n]othing in *Ives* precludes this court from evaluating the relevant evidence and concluding that the trade dress here in issue is nonfunctional." (A. 39-40)

Viewed properly, then, the only issue presented by Bolar with respect to functionality is whether the Third Circuit erred in affirming the District Court's fact finding of nonfunctionality as not being clearly erroneous—an issue that hardly merits the sparing exercise of this Court's certiorari jurisdiction. Indeed, in *Ives* itself, Justice White stated that "if the issue presented in the petitions for certiorari had been whether the clearly erroneous standard, although properly invoked, was erroneously applied, it is doubtful in my mind that this fact-bound issue would have warranted certiorari." (456 U.S. at 859) Justice White's skepticism reflects this Court's long-standing view that "[w]e do not grant certiorari to review evidence and discuss specific facts." *United States* v. *Johnston*, 268 U.S. 220, 227 (1925). As this Court's "repeated pronouncements" have made clear, "it 'cannot undertake to re-

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dent review" of that claim. (456 U.S. at 858-59) Had the Court held that drug trade dress was functional as a matter of law, that remand would have been unnecessary. Nor did the Second Circuit on remand view this Court as holding that drug trade dress was functional as a matter of law. Rather, the Second Circuit affirmed the dismissal of plaintiff's § 43 claim on the basis of the trial judge's *factual* findings which the Second Circuit held could not be "label[ed] . . . clearly erroneous." (A. 59) In this connection, it is noteworthy that, as the *amicus* NAPM correctly states, the Second Circuit's remand opinion was "not published per Second Circuit Rule 0.23" (NAPM Br. at 2)—which means that "each judge believe[d] that no jurisprudential purpose would be served" by such publication. (2d Cir. R. 0.23) If, in fact, the Second Circuit had read *Ives* to hold that all drug trade dress was functional as a matter of law, it surely would have been of sufficient "jurisprudential" import to have warranted the opinion's publication.

view concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error.' " *Berenyi* v. *Immigration Director*, 385 U.S. 630, 635 (1967), *quoting Graver Mfg. Co.* v. *Linde Co.*, 336 U.S. 271, 275 (1949). No such "obvious and exceptional" showing has been or could be made here given the ample evidentiary support for the District Court's nonfunctionality finding. (*See* A. 19-24)

2. *Secondary Meaning*

Equally bereft of merit is Bolar's contention that the decision below "conflicts" with *Ives* "as to the standards for establishing 'secondary meaning' of drug color." (Petition at 20) Indeed, this Court did not even address the issue of secondary meaning in *Ives*, except for a passing footnote to this Court's background recitation of the trial court's § 43(a) holding (456 U.S. at 851 n.11)—a holding which this Court never reached. (*Id.* at 858-59) Moreover, the District Court here expressly quoted the definition of secondary meaning contained in that footnote in "[a]pplying the well-settled legal criteria for determining secondary meaning. . . ." (A. 24, 40) Bolar is thus dead wrong in asserting that the trial court "specifically declined to follow the legal standards for . . . 'secondary meaning' of drug appearance affirmed by this Court in [*Ives*]." (Petition at 3)[20]

As in the case of nonfunctionality, what Bolar is actually quibbling with is the District Court's assessment of the evidence with respect to secondary meaning, its factual findings with respect to that issue and the Third Circuit's affirmance of those findings as not being clearly erroneous. As we have already demonstrated with respect to nonfunctionality, those are plainly not matters which warrant this Court's review. (*See* pp. 16-17, *supra*) Given the ample evidentiary support for the

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20 Nor, for the reasons already discussed with respect to nonfunctionality, *see* p. 16 n.19, *supra*, is Bolar correct in contending that the decision below with respect to secondary meaning conflicts with the Second Circuit's decision on remand in *Ives*.

District Court's secondary meaning findings (A. 14-18, 24-28, 40-42), Bolar has not made, nor could it make, the "very obvious and exceptional showing of error" which is required before this Court will "undertake to review concurrent findings of fact by two courts below. . . ." *Berenyi* v. *Immigration Director, supra*, 385 U.S. at 635.[21]

In sum, not only is there no conflict between *Ives* and the lower courts' finding with respect to the tort of "unprivileged imitation," but that finding—which alone was sufficient to support the District Court's preliminary injunction—was eminently correct.[22]

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21 Even a cursory review of the District Court's opinion demonstrates that its fact findings concerning secondary meaning were not clearly erroneous. (A. 14-18, 24-28, 40-42) Indeed, they were based on indisputable evidence of the kind the courts throughout the Circuits have traditionally relied upon in determining secondary meaning—including defendant's intentional copying without legitimate justification. Ideal Toy Corp. v. Plawner Toy Mfg. Corp., 685 F.2d 78, 82 (3d Cir. 1982); Faberge, Inc. v. Saxony Prods., Inc., 605 F.2d 426, 428 (9th Cir. 1979); W.E. Bassett Co. v. Revlon, Inc., 435 F.2d 656, 661 (2d Cir. 1970); Truck Equip. Serv. Co. v. Fruehauf Corp., 536 F.2d 1210, 1220 & n.13 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976); Midway Mfg. Co. v. Dirkschneider, 543 F. Supp. 466, 485-87 (D. Neb. 1981). *See* J. McCarthy, *Trademarks & Unfair Competition* § 15.16 (1973); J. Gilson, *Trademark Protection & Practice* § 2.09[1] (1982). Bolar's assertion that the District Court found "mere copying" to be sufficient proof of secondary meaning (Petition at 26) ignores not only the other probative evidence on the issue, but also the trial judge's rejection of the testimony of Bolar's president that it copied APRESAZIDE's trade dress for legitimate reasons (A. 18, 29-31)—a matter of credibility uniquely within the trial judge's province. Berenyi v. Immigration Director, *supra*, 385 U.S. at 635-36. Similarly supported by substantial record evidence was the District Court's finding that the market presence of Pfizer's antihypertensive MINIPRESS did not preclude a finding of secondary meaning in APRESAZIDE's trade dress. (A. 27-28, 41-43)

22 Bolar's contention that the "lower courts improperly based a nationwide injunction on New Jersey state law" (Petition at 26) ignores the fact that the elements of "unprivileged imitation"—nonfunctionality and secondary meaning—are the same under § 43(a) of the Lanham Act, as this Court itself indicated in *Ives*. (456 U.S. at

B. The Lower Courts' Alternative Finding With Respect to the Tort of "Passing Off" Presents No Conflict With This Court's Narrow Disposition in *Ives*.

Although noting that it was "unnecessary" to address CIBA's second claim in light of its favorable finding on "unprivileged imitation," the District Court—"for the sake of completeness"—held in the alternative that CIBA had also established the requisite likelihood of success with respect to the independent tort of "passing off" under both § 43(a) and New Jersey law. (A. 44-47) The Third Circuit, however, expressly declined to address the District Court's "passing off" holding under § 43(a), finding instead that its conclusions with respect to "passing off" were "mandated" by New Jersey law. (A. 4 n.1) Accordingly, because the Third Circuit's affirmance with respect to "passing off" rested solely on an alternative state law ground, there is no conflict with *Ives*. Nor is the Third Circuit's interpretation of New Jersey law worthy of certiorari. As this Court declared in *Huddleston* v. *Dwyer*, 322 U.S. 232, 237 (1944), "ordinarily we accept and therefore do

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850-51) Nor is Bolar correct that the decision below will stifle legitimate competition. (Petition at 13-15, 27 n.10) On the contrary, Bolar is entirely free to market its generic version of APRESAZIDE in distinctly different colored capsules and to compete with CIBA's products on the merits—in terms of price, quality and reputation—just as another drug manufacturer has successfully done without appropriating APRESAZIDE's trade dress. (A. 20) Similarly, there is no merit to Bolar's argument that this Court's decisions in Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964), and Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234 (1964), preclude trade dress protection under the federal and state laws of unfair competition. Indeed, the Second Circuit in *Ives* explicitly rejected that contention (Ives Laboratories, Inc. v. Darby Drug Co., 601 F.2d 631, 639-44 (2d Cir. 1979)), and this Court, by remanding for an "independent review" of plaintiff's § 43(a) and "state unfair competition" claims (456 U.S. at 858-59), implicitly did so as well. *Accord*, SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1064-65 (3d Cir. 1980); Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd., 604 F.2d 200, 203-04 (2d Cir. 1979); Truck Equip. Serv. Co. v. Fruehauf Corp., 536 F.2d 1210, 1214-15 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976); *In re* Honeywell, Inc., 497 F.2d 1344, 1347-49 (C.C.P.A.), *cert. denied*, 419 U.S. 1080 (1974).

not review, save in exceptional cases, the considered determination of questions of state law by the intermediate federal appellate courts." *Accord*, *Estate of Spiegel* v. *Commissioner*, 335 U.S. 701, 707-08 (1949).[23]

Moreover, even if the Third Circuit had reached the District Court's "passing off" holding under § 43(a) and had affirmed that holding, there would still be no conflict with *Ives* because (1) *Ives* did not involve a claim of "passing off" under § 43(a); and (2) the District Court not only found that Bolar "reasonably anticipated" that its look-alike product would be illegally substituted for CIBA's APRESAZIDE, but also that it "actually intended" that result. (A. 30-31, 46-47)

As already noted, this Court never reached plaintiff's § 43(a) claim in *Ives*. The reversal of the Second Circuit for failure to comply with Rule 52's clearly erroneous standard was limited to plaintiff's claim of contributory trademark infringement under § 32 of the Lanham Act. Thus, this Court stated that "the judgment of the Court of Appeals that the petitioners violated § 32 of the Lanham Act is reversed." (456 U.S. at 858) In contrast, the case was remanded to the Second Circuit for an "independent review" of plaintiff's § 43(a) claim because—as this Court was at pains to note—that provision "prohibits a broader range of practices than § 32, as may the state unfair competition law. . . ." *Id.* Accordingly, *Ives*' purported rejection of the "reasonable anticipation" standard was confined, on its face, to § 32 claims of contributory trademark infringement.

In applying the "reasonable anticipation" standard for the tort of passing off under § 43(a), the District Court followed

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23 Bolar misstates the record by asserting that New Jersey has "no interest in or subject matter jurisdiction over" its look-alike sales because it allegedly "intentionally avoided selling its product into New Jersey." (Petition at 4) Not only did Bolar prepare sworn applications for inclusion of its look-alike product on the New Jersey Formulary in order to permit New Jersey pharmacists to substitute it for CIBA's APRESAZIDE, but Bolar's president testified that if Bolar were not enjoined, "we would sell [our look-alike product] in *any* place in the country." (*See* R. 240, 1932-37; emphasis added)

the lead of *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), where the Third Circuit gave concretion to *Ives*' statement that that provision outlaws a "broader range" of conduct than does § 32. There, citing Judge Hastie's "leading" opinion in *L'Aiglon Apparel, Inc.* v. *Lana Lobell, Inc.*, 214 F.2d 649 (3d Cir. 1954), the Third Circuit explained that "[i]t is well established that Section 43(a) proscribes not only acts that would technically qualify as trademark infringement, but also unfair competitive practices involving actual or potential deception," including the tort of passing off. (625 F.2d at 1065) Because of that "broader" reach, the "reasonable anticipation" standard promotes § 43(a)'s purposes. For, as the District Court reasoned:

> "By putting in the hands of pharmacists, through intermediate wholesalers and distributors, a product which admittedly will facilitate illegal passing off, Bolar knowingly creates a real potential for deception, whether or not it is technically guilty of contributory trademark infringement." (A. 46)

Moreover, even if *Ives* overruled the "reasonable anticipation" standard for the tort of passing off under § 43(a), and even if the Third Circuit had reached the District Court's passing off holding under § 43(a) and had affirmed it, there would still be no conflict with *Ives* because of the District Court's "[a]lternative" finding that "[t]here is a substantial likelihood that plaintiff will succeed in proving that Bolar *actually intended* to facilitate . . . illegal substitution among pharmacists in order to increase its sales." (A. 30-31, 46-47; emphasis added) For, as the District Court explained (A. 46), that finding satisfies even the higher "intent" standard for contributory infringement advanced by Justice White in *Ives* (456 U.S. at 860), and the one which Bolar contends that the majority opinion in fact adopted. (Petition at 11-13) Nor is the District Court's "alternative" finding as to Bolar's actual intent worthy of certiorari review, even assuming that the Third Circuit had reached the matter. For as this Court has held, the issue of intent "is a pure question of fact, subject to

Rule 52's clearly-erroneous standard," *Pullman-Standard* v. *Swint*, 456 U.S. 273, 287-88 (1982), which "depend[s] peculiarly upon the credit given to witnesses by those who see and hear them." *United States* v. *Yellow Cab Co.*, 338 U.S. 338, 341 (1949).[24]

Finally, and apart from all else, it would be inappropriate for this Court to grant certiorari to review the District Court's § 43(a) "passing off" holding *unless* it were also prepared to conclude that the District Court's alternative holding with respect to "unprivileged imitation" merited certiorari review. For otherwise the Court would be violating its venerable rule against advisory opinions, since that alternative holding provides an independently sufficient basis for affirming the order below.

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24 Nor is there any doubt that the District Court's finding in this regard could withstand scrutiny under the clearly erroneous test. (*See* A. 18, 29-31, 46-47) In brief, Bolar's president testified that Bolar's sales would be substantially greater if it copied APRESAZIDE's trade dress rather than marketing non-look-alike generic versions, and that Bolar's wholesale customers "prefer[red]" it to duplicate APRESAZIDE's trade dress in order to increase their sales. (R. 206-07, 218-20, 620-23) Given the undisputed testimony of Bolar's medical expert that patients invariably accept different-looking generic substitutes if proper medical and pharmaceutical procedure is followed (A. 22-23)—that is, if they are told that the generic equivalent is chemically and therapeutically identical—the only plausible inferences are (1) that Bolar intended that the substantial sales increase it anticipated from selling its product in a look-alike version would be achieved through the facilitation of *illegal*, not legal, substitution; and (2) that, under the recent formulation in Sony Corp. v. Universal City Studios, Inc., 52 U.S.L.W. 4090, 4095 n.19 (U.S. Jan. 17, 1984), Bolar supplied its look-alike product—"which could readily be passed off"—to customers who it knew would engage in illegal substitution. When coupled with the trial judge's unique opportunity to evaluate the credibility and demeanor of Bolar's president—whose testimony was impeached no fewer than *seven* times by his flatly inconsistent deposition testimony—his finding of actual intent to facilitate illegal substitution had more than sufficient evidentiary support to pass muster under Rule 52(a). (*See* A. 11; R. 188-90, 195-97, 204, 206-18, 221-25, 233-34, 262-66)

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Petition should be denied.

Dated: February 15, 1984

Respectfully submitted,

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ADDENDUM

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION, Plaintiff,	:	Before: Hon. H. Lee Sarokin
	:	Civil Action No. 82-788
vs.	:	NOTICE OF APPEAL
BOLAR PHARMACEUTICAL CO., INC., Defendant.	:	

Notice is hereby given that Bolar Pharmaceutical Co., Inc., appeals to the United States Court of Appeals for the Third Circuit from the Final Judgment filed on December 23, 1983, and entered on December 28, 1983, granting Ciba-Geigy's application for a permanent injunction and entering final judgment in favor of Ciba-Geigy.

Respectfully submitted,

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Dated: January 19, 1984

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PROOF OF SERVICE

I, Richard A. De Sevo, an attorney for Respondent herein, and a member of the Bar of the Supreme Court of the United States as of February 21, 1984, do hereby certify that on the 15th day of February 1984, I served three copies of the foregoing Brief for Respondent CIBA-GEIGY Corporation in Opposition to Petition for Writ of Certiorari and the addendum attached thereto, by mailing and depositing same in the United States Post Office or mail box, with first class postage prepaid, in a duly addressed envelope, to Robert B. Jones, Fitch, Even, Tabin & Flannery, 135 South LaSalle Street, Chicago, Illinois 60603. I further certify that all parties required to be served have been served.

Dated: February 15, 1984

/s/ Richard A. De Sevo

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CLERK

No. 83-1163

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

CIBA-GEIGY CORPORATION,

Respondent.

BRIEF *AMICUS CURIAE* OF THE AMERICAN ASSOCIATION OF RETIRED PERSONS IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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STATEMENT OF INTEREST

The American Association of Retired Persons ("AARP"), of 1909 K Street, N.W., Washington, D.C. 20049, is a not-for-profit membership corporation of more than 15 million persons over the age of 50. AARP is the largest organized group of older Americans in the country. In representing the interests of its members, AARP seeks to: (a) enhance the quality of life for older persons; (b) promote independence, dignity and purpose for older persons; (c) lead in determining the role and place of older persons in society; (d) sponsor research on physical, psychological, social, economic and other aspects of aging; and (e) represent the point of view of older persons as consumers of goods and services.

In the area of health care, AARP's overriding interest is to foster and promote efficient delivery to older persons of the best possible products and services at the least possible cost, and to make those products and services readily available to persons living within fixed and limited incomes. AARP has steadfastly maintained that elimination of anti-competitive barriers in the drug industry is essential to the achievement of this goal.[1]

REASONS FOR GRANTING THE WRIT

I

THIS CASE PRESENTS IMPORTANT QUESTIONS OF FEDERAL LAW WHICH SHOULD BE SETTLED BY THIS COURT

The social and economic issues raised by this case—including containment of the cost of pharmaceuticals and ensuring that the functional benefits of color-identification of drugs will be

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[1] In support of that goal, AARP has often participated in litigation in this area. For example, AARP submitted an *amicus curiae* brief to this Court in support of generic drug manufacturers in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982). In addition, AARP intervened on behalf of the State of New York in defense of New York's generic drug

available to consumers—are critical to all consumers of drug products, particularly older Americans. In consequence, this case presents important questions of law which should be settled by this Court.

The Anti-Competitive Impact of The Decision Below Will Be Especially Strong Upon Older Americans

AARP's deep concern about the disposition of this petition stems from its involvement with health-related matters affecting older persons and its representation of the consumer interests of older Americans. Due to their advanced age, older Americans depend on regular or frequent administration of pharmaceuticals to maintain their continued health. At the same time, many of those individuals are retired persons who live on low or fixed incomes. Because of the need to contain the already high and rapidly increasing cost of health care, allowing the decision below to remain in effect would be a serious blow to the health and welfare of AARP's fifteen million members and older Americans in general.

The high cost of drugs is particularly onerous to older Americans because Medicare and other insurance often covers only a small portion of that cost. For example, Medicare does not pay for "out-of-hospital prescription drugs." As a consequence, in 1981, older Americans were not reimbursed for 82 percent of the cost of drugs that they purchased. This out-of-pocket ex-

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substitution law, *Pharmaceutical Manufacturer's Association v. Whalen*, 54 N.Y. 2d 486 (1981). Recently, AARP filed a brief in support of a generic drug trade association in an effort to invalidate a Food and Drug Administration policy which works to inhibit the availability of generic drug equivalents. *National Association of Pharmaceutical Manufacturers v. Heckler*, No. 83-4817 (S.D.N.Y., filed June 24, 1983).

AARP has also participated in the legislature process and made its views known to Congress. *See, e.g., Statement on Scientific Literature New Drug Applications Before the Subcommittee on Oversight and Investigation of the House Committee on Energy and Commerce*, 97th Congress, 1st Session (March 10, 1981); *Statement in Support of the Drug Price Competition Act of 1983, H.R. 3605, Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce*, 98th Congress, 1st Session (July 25, 1983).

pense constituted older Americans' fourth largest self-paid health expenditure.[2]

The availability of generic drug equivalents, which usually sell for a fraction of their brand name counterparts,[3] has enabled AARP's members and other consumers to significantly reduce their prescription drug expenditures. AARP believes that the law should not only permit the availability of generic drugs, but should also enable such drugs to compete effectively with brand name products.

For a variety of reasons, brand name manufacturers enjoy a significant advantage in the market for the drugs that they

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[2] *Health Care Financing Administration: Personal Health Care Expenditures Data*, prepared for Senate Aging Committee (Calendar 1981).

HCFA data also shows that persons aged 65 and over, while comprising only 11 percent of the population, incur between 24 and 30 percent of all drug expenditures. On average, an older American will buy prescription drugs 18 times a year, which is two and one half times as often as a person under age 65.

Many older Americans are hard-pressed to keep pace with prescription drug prices, which in 1982 rose by 12 percent according to the Consumer Price Index for All Urban Consumers as reported by the Bureau of Labor Statistics, an increase far in excess of the overall CPI for that year. The United States Census Bureau found that in 1982 the median income of persons 65 and over was 48 percent that of other Americans. *See*, "Money, Income and Poverty Status of Families and Persons in the U.S.: 1982". Report by United States Census Bureau (Series p. 60 No. 140). In 1982, Social Security recipients received a cost of living adjustment of 7.4 percent, 47 Fed. Reg. 20863 (1982), an increase insufficient to cover the increase in drug costs. Older Americans who need prescription medicine and are unable to afford it are often forced to endanger their health either by "stretching" their medication (taking it less frequently than prescribed) or by forgoing certain medicines entirely.

[3] *See, e.g.*, Chemical Marketing Reporter, March 7, 1983, at 14.

One indication of the need for encouraging vigorous competition in the prescription drug industry is the fact that the producer price index for prescription drugs showed an increase of approximately 11% for the third consecutive year in 1983, while at the same time, according to the Bureau of Labor Statistics, the cost of manufacturing prescription drugs declined by 1.1% in 1983.

"Price increases in the prescription area were not linked to any corresponding increase in intermediate cost for pharmaceutical manufacturers. In fact, as measured by the Bureau of Labor Statistics' producer price index for medicinal and botanical chemicals, bulk pharmaceutical material prices declined 1.1% in 1983." Weekly Pharmacy Reports: "The Green Sheet", Jan. 30, 1984 (Citing McKesson's Pharmaceutical Data Services (PDS)).

produce. Securing a patent confers a seventeen year monopoly upon a brand-name drug. During that time, the manufacturer will typically conduct an advertising campaign targeted at physicians. This generally creates a predisposition in favor of the brand-name product among physicians who will write their prescriptions accordingly.[4] In this case, Ciba-Geigy's Apresazide enjoyed a period of five and one half years during which it had no competition from a generic equivalent.

In recognition of the competitive advantage accruing to brand name manufacturers, the legislatures of forty-nine states have adopted so-called "generic drug substitution" statutes which either require or allow the dispensing pharmacist to substitute the generic drug, unless the prescribing physician directs otherwise. These statutes are evidence of the pervasive local interest in fostering effective competition in the pharmaceutical market to achieve some measure of cost containment. The Third Circuit has seriously prejudiced that interest by effectively granting brand-name manufacturers a perpetual monopoly over the color in which the capsules or tablets of their drugs are produced.

The color of drug capsules or pills involves far more than aesthetics; it is a vital competitive characteristic. During the period in which a patent is in effect, brand-name manufacturers typically select a color which becomes identified with the particular drug in the eyes of dispensers such as physicians, hospitals and pharmacists, as well as to patients themselves. After the patent monopoly period expires, the introduction of a generic equivalent capsule in a different color is certain to meet substantial resistance on the part of dispensers and patients alike. Requiring such a different color will therefore foreclose the generic competitor from a substantial portion of the market.

Thus, it is predictable that the Third Circuit's decision, which will severely restrict the ability of generic manufacturers to

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[4] *See, Chemical Marketing Reporter*, March 7, 1983, at 11. ". . . they (physicians) are creatures of habit, like everyone else. If you've been using the same product for 10 to 15 years, you may not necessarily write the prescription in a generic manner." (Quoting Ronald M. Nordmann, Vice President and Senior Drug Analyst for Oppenheimer & Co.).

market their drugs in the same accustomed colors and trade dress used by the brand-name producers, will inhibit competition and inevitably lead to increased prices. This threat to the continued availability of lower-priced, bioequivalent generic drugs, and the absence of downward pressure on prices caused by their competition with brand-name drugs, seriously prejudices older persons—a category of Americans with often the greatest need for drugs, but the most limited means of paying for them.

Consumers Should Not Be Deprived of The Functional Benefits of Color Identification of Drugs

As witnesses below testified, and as this Court noted in its decision in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 853 (1982), the colors used in drug capsules serve important functions.

In the first place, the capsule or tablet color often identifies the therapeutic effect of the medicine to the patient. Since the brand-name product, dressed in the color of the capsule containing it, is the exclusive source of a drug during (and often for some time beyond) its patent life, many patients become accustomed to identifying that drug as "my little blue heart pill."[5] When a bioequivalent generic drug becomes available only in a different color, considerable resistance with respect to the generic alternative may result, event where the patient understands the concept of generic drugs and is aware that generic substitution is being made.[6] This may lead to a lack of patient acceptance of the generic substitute.[7] Such real or perceived patient unwillingness to use the "off-color" generic substitute

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[5] As this Court pointed out in *Inwood*, the District Court there found that "many elderly patients associate color with therapeutic effect." 456 U.S. at 853. In the instant case there is also ample evidence to support this conclusion. *See*, Pet. Br. pp. 7, 18.

[6] *See*, Pet. Br. p. 9.

[7] The District Court acknowledged that "(a) patient who has utilized the brand-name drug over a period of time may accept the generic drug more readily if it looks the same as the brand-name." *Ciba Geigy Corp. v. Bolar Pharmaceutical Co.*, 547 F.Supp. 1095 at 1098 (D.N.J. 1982). Pet. App. p. 9.

may lead physicians to prescribe the brand-name drug to insure that patients will take the necessary medication.

In its opinion, the District Court suggested that patients would overcome their resistance by calling the physician and receiving an explanation.[8] But even if this process would solve the problem in some individual cases, it is likely that instead of devoting their limited time to such telephone calls, physicians would insist that prescriptions be filled with brand-name drugs, especially since they have no personal stake in favoring the use of generic drugs. Thus, concerns about ensuring patient compliance with drug prescriptions may well lead to a decrease in generic substitution, thereby denying many patients access to lower priced generics.[9]

In addition to identifying a medicine's therapeutic value to the patient, after a prolonged period of use the color of a drug becomes part of the patient's routine. Even if a patient eventually accepts a variation in a drug's color, that acceptance may take place only after considerable anxiety and confusion. This may deprive the patient of the important "placebo effect" produced by the drug, i.e., the psychosomatic healing which comes from the patient's confidence and assurance that the medication he is taking will help him.

Another reason why maintaining continuity in the color of drugs is important is that many elderly patients who take multiple medications identify each drug by its color. In fact, where drugs of differing therapuetic effect are comingled in the same container, color becomes the only means of properly identifying each one.[10] Variations in color between brand-name and generic drugs which constitute the same medicine would upset the procedures employed by many older patients to identify or recognize their drugs, and create confusion and possible mistakes in adhering to prescriptions.

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[8] *Id.*, at 1104, Pet. App. p. 22.

[9] The District Court also acknowledged that "[t]he 'look-alike' drug becomes more saleable, because it makes it easier for both the doctor and pharmacist to substitute the generic drug." 547 F Supp. at 1098.

[10] *See, Inwood*, 456 U. S. at 853. *See also*, Pet. Br. pp. 8, 18.

Indeed, the potential for confusion where drugs with the same therapeutic effect have different colors has led hospitals, pharmacies and wholesalers to refuse to purchase generic drugs colored differently from brand-name drugs. As a result of this practice, the availability of lower-cost drugs to older persons has already been impaired.

Finally, uniform drug coloring can save lives by helping to identify the drug involved in overdoses to physicians and emergency personnel acting in life-threatening situations.

Viewed in this social context, the decision below can only have a pernicious impact upon the well-being of older Americans. Simply stated, the courts below chose to ignore or disparage the significant role that drug color plays in the competitive marketplace and the benefits that generic equivalents in the same color as brand-name drugs bestow upon their users. Should the Third Circuit's decision be allowed to stand, it will deal a severe blow to generic drug substitution and to the welfare of millions of consumers and older Americans. For those reasons, the questions of federal law that are raised by the case merit prompt review and definitive determination by this Court.

II

THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISION IN INWOOD AND DECISIONS OF THE SECOND CIRCUIT

As pointed out by petitioner herein (in whose arguments for the granting of certiorari AARP joins), the decision below conflicts with the decision of this Court in the *Inwood* case, and with the decision of the Second Circuit in that case following remand, *Ives Laboratories, Inc. v. Darby Drug Co.*, 697 F.2d 291 (2d Cir. 1982).

Because of the acute social need to foster the availability and use of generic drug substitutes, it is especially important for this Court to resolve those conflicts on such critical legal questions as the proper standards that courts should employ when they

consider the "functionality" and "secondary meaning" of drug color, and to lay to rest any doubt as to its rejection of the "reasonable anticipation" standard for prohibiting the manufacturing of generic drugs with the accustomed appearance of brand-name drugs.

One issue of particular importance to AARP concerns the Third Circuit's application of the law respecting contributory infringement under the Lanham Act. In effect, the courts below restrained Bolar because of the possibility that a few pharmacists might intentionally dispense Bolar's generic product under the guise of the brand-name drug in pursuit of their own economic advantage. The District Court concluded that Bolar had "reason to anticipate the passing off of look-alike product," and speculated that Bolar duplicated Ciba's Apresazide capsule color in order to facilitate such illegal substitution of pharmacists. This reasoning is in clear conflict with the standard adopted by the Second Circuit,[11] and with the governing decisions of this Court.[12]

To guard against the possibility that some pharmacists might illegally substitute generic drugs, the decision below imposed a cure that is worse than the disease. It effectively granted a perpetual monopoly over the color of drug capsules and tablets to brand-name drug manufacturers and, in the process, gave them an unfair advantage over generic competitors. That result is at odds with the policy expressed by the states which have enacted generic substitution laws.[13] It seems self-evident that the social benefits which will accrue from permitting copying of

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[11] In *Ives Laboratories, Inc. v. Darby Drug Co., Inc., et al.*, 601 F.2d 631, 636 (2d Cir., 1979), the Court held that liability would result if the defendant "suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' (the brand-name) mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practice just described." Bolar does not sell or promote its products to pharmacists, so it is difficult to see how it could be liable under this standard.

[12] *See, Inwood*, 456 U.S. at 850 n.13 (1982); *Sony Corp. v. Universal City Studios*, 52 U.S.L.W. 4090, 4095, n.19 (Jan. 17, 1984).

[13] It is also inconsistent with this Court's reasoning that once a product may be legally manufactured by anyone, the original producer does not have an exclusive right to the demand for the product or its goodwill. *See, Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 at 120 (1938).

the color of drug capsules and the facilitation of generic drug substitution would far outweigh any cost from possible illegal passing off of generic drugs as their brand-name counterparts by a few dishonest pharmacists.[14]

AARP had believed that questions relating to the size, shape and color of generic drugs had been settled in favor of duplication of drug trade dress by the *Inwood* decision. As those issues have apparently not been definitively resolved, the Court should resolve them now to protect society's interest in fostering the use of and availability of generic drug substitutes and to enable generic drug firms to serve that interest by formulating their marketing decisions with confidence in the nature of the governing rules.

CONCLUSION

To that extent that generic manufacturers will become unable to compete effectively with the brand-name producers because of the monopoly in capsule color conferred by the Court of Appeals in this case, the brand-name manufacturers will enjoy a restoration of the product monopoly which expired along with their patents. Such a result would be catastrophic for cost containment in the pharmaceutical industry, and would be paid for in large part by older persons—the group of Americans least able to afford it.

Even if generic drug manufacturers manage to remain in the market despite the anti-competitive impact of the decision below, drug identification by color will no longer be possible. As a

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[14] In imputing liability to Bolar, the District Court reasoned that "[t]here are laws against turning back mileage indicators on used cars, not because all dealers do it, but because some have and will", 547 F.Supp. at 1117, Pet. App. p. 49. But laws such as those are aimed at the ones who actually commit the illegal acts. Illegal drug substitution or "passing off" is unlawful and should remain so, and the individuals who commit such acts should be punished. However, otherwise proper conduct should not be proscribed because it could conceivably facilitate illegal conduct by others. In fact, drawing the logical conclusion from the court's analogy would require outlawing the sale of used cars.

result, consumers will be deprived of the functional benefits of color-identification, a burden that once again will fall with particular harshness upon older persons.

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Dated: New York, New York
February 13, 1984

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APPENDIX A

No. 83-1163

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,

vs.

CIBA-GEIGY CORPORATION,
Respondent.

CONSENT TO FILE BRIEF OF AMICUS CURIAE

Pursuant to the Rules of the Supreme Court of the United States, Rule 36.1, the undersigned counsel for the parties in the above-captioned matter hereby consent to the filing of a brief by the American Association of Retired Persons as Amicus Curiae in support of the Petition for a Writ of Certiorari.

Dated: February 9, 1984

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N.B. Original filed with court

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No. 83-1163

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CIBA-GEIGY CORPORATION,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF AMICUS CURIAE OF THE ILLINOIS PHARMACISTS ASSOCIATION

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BRIEF AMICUS CURIAE OF THE ILLINOIS PHARMACISTS ASSOCIATION

INTEREST OF THE ILLINOIS PHARMACISTS ASSOCIATION

The Illinois Pharmacists Association[1] ("IPhA") is a professional society of pharmacists having a membership of

[1] The administrative offices of the IPhA are located at Suite 400, 222 West Adams Street, Chicago, Illinois 60606.

over two thousand five hundred pharmacists engaged in all aspects of pharmacy practice and teaching throughout the State of Illinois.

The Third Circuit decision in this case grants a nationwide monopoly on the appearance characteristics of drug dosage forms which function to identify the drugs themselves. It authorizes failure to select and promote useful generic names for drugs. The decision of the Third Circuit will accordingly adversely affect drug product selection, pharmacy communication with patients and public health and safety in the State of Illinois.

The IPhA submits this brief in support of the Petition for Certiorari, pursuant to Rule 36.1 of the Rules of this Court, written consent of the parties being submitted herewith.

The IPhA's position is that the Third Circuit's Opinion in this case should be overturned to the extent that it affirmed a ruling based on a series of presumptions including the presumptions that Bolar acted in bad faith merely because it elected to manufacture a generic drug in publicly accustomed colors and that Bolar intended to facilitate illegal substitution by pharmacists.[2] Since the rejection of the "reasonable anticipation" standard by this Court in *Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982) as it applied to Section 32 of the Lanham Act, the use of the "reasonable anticipation" standard in a Section 43 Lanham Act case should also be found to be erroneous. The use of presumptions

[2] The IPhA certainly does not condone any illegal activity by any pharmacist and submission of this brief should in no way be construed as a step taken in support of or in order to facilitate any potential illegal activity.

in this case is nothing more than use of the "reasonable anticipation" standard and should consequently be rejected by this Court as inconsistent with its opinion in the *Inwood* case.

As an affiliate of the 55,000 member American Pharmaceutical Association, the IPhA has supported the policy of the American Pharmaceutical Association to oppose the granting of monopolies in the appearance of a drug dosage form, because drug appearance identifies the drug itself, not its source. The IPhA concurs with the official statement of the American Pharmaceutical Association to Congress opposing monopolies on drug product appearance:

> [C]reating a monopoly as to the appearance characteristics of a drug dosage form . . . would be expected to drastically reduce the number of multisource drug products, thereby limiting the benefits of competition for patients in the 45 states [now 49] which have laws permitting pharmacists to engage in drug product selection for the benefit of their patients. This could also have a negative impact on patient compliance with prescribed drug regimens, since patients associate drug identity with drug product appearance. Furthermore . . . [granting a monopoly on drug appearance] would exacerbate the problem of drug identification in emergency situations such as accidental poisonings" [Def. Ex. 26, Trial Record, p. 837].

In 1977, recognizing that physicians prescribe by drug "brand name" when referring to the medication itself because of habit or unfamiliarity with generic names, Illinois joined the great majority of other states by enacting its drug product selection law, Illinois Revised Statutes Chapter 111, Paragraph 4033. This statute provides that pharmacists may dispense a lower cost drug for a "brand name" prescription under specified conditions.

The overall appearance of a drug dosage form by which it is recognized and identified must be distinguished from source identification. The IPhA also strongly supports the position of the American Pharmaceutical Association that "the name, trademark, number or code" of the drug manufacturer should be used on the dosage form itself [Def. Ex. 26, Trial Record, p. 839]. In this case, the generic manufacturer Bolar prominently printed its logo and National Drug Control Identification Number twice on each capsule, and packaged its product in distinctive containers, clearly identifying itself as the manufacturer.

The opinion of the Third Circuit interferes with the valid state policy of Illinois to facilitate generic drug substitution. The availability of generic drugs promotes competition in the pharmaceutical marketplace, with the resultant effect of cost containment. The Third Circuit decision limits the pharmacist, physician and patient seeking the drug dosage form in a uniform accustomed appearance by which it is recognized, to a single, monopoly source. Requiring generic drugs to have a different physical appearance from that by which the drug has been recognized and identified by patients and health care professionals will have a serious anticompetitive impact on the generic drug industry.

ARGUMENT

A.

THE APPEARANCE CHARACTERISTICS OF A DRUG DOSAGE FORM SERVE TO IDENTIFY THE DRUG ITSELF AND SHOULD NOT BE MONOPOLIZED.

The functionality of the accustomed appearance for drug identification was properly expressed by this Court in its approval of the District Court decision in *Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), as follows:

> . . . that the blue and blue-red colors were functional to patients as well as to doctors and hospitals: many elderly patients associate color with therapeutic effect: some patients co-mingle medications in a container and rely on color to differentiate one from another: colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs [456 U.S. 844 at 853].

This utility of the accustomed appearance characteristics of a drug dosage form, which is unrelated to identification of the manufacturer of the drug, was confirmed in the present *Ciba-Geigy v. Bolar* case by the testimony of Dr. James O'Donnell[3] [Trial Record, pp. 351-377, 422-425].

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[3] In addition to serving as a pharmacist member of the Generic Drug Technical Advisory Council of the State of Illinois and an experienced poison control specialist of the Chicago Poison Control Center, Dr. O'Donnell also presently serves as the Vice President for Professionals Affairs of the IPhA. Dr. O'Donnell did not, however, testify on behalf of the IPhA.

As pointed out by this Court in its landmark *Kellogg Co. v. National Biscuit Co.* ("Shredded Wheat") decision:

> [A] particular manufacturer can no more assert exclusive rights in a form in which the public has become accustomed to see the article and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind [305 U.S. 111, 118].

This Court affirmed in *Inwood, supra*, that there can be no grant of monopoly unless the "manufacturer can show that in the minds of the public, the primary significance of a product feature or terms is to identify the source of the product rather than the product itself" *Id.* at 851. The primary significance of the appearance of a drug dosage form is drug identity, not source.

This issue was crystallized by Chief Justice Burger in his question to the Justice Department Attorney, Mr. Ganzfried, during oral argument in the *Inwood v. Ives, supra* as to the functionality of color for drug product identification as opposed to source identification:

> *Mr. Ganzfried*: For example, if I may take one that appears before me, a question of judicial robes. If there were one company that made judicial robes and made them black, would the second company that made them have to make them green? The question is do you identify the color with the product or do you identify it with the producer; and that is the issue in this case.
>
> *Question*: Well, in common human experience what would be, in your view, the reaction to people being handed green aspirin?
>
> *Mr. Ganzfried*: They would think it was something other than aspirin [Oral Argument Transcript, February 22, 1982, p. 29].

This is in fact the reaction of patients who, knowing a generic drug is being dispensed, receive a drug which they do not recognize. They think it is the wrong medicine. Forcing generic competitors sell green aspirin, or another drug of unfamiliar appearance because physicians and pharmacists may be able to convince most patients that the drug may have another appearance, is like forcing a competitor to make green judicial robes because judges can be convinced that it is still a judicial robe. It can usually be done, but it is an artificial barrier to competition.[4]

B.

A USEFUL GENERIC NAME IS REQUIRED FOR COMMUNICATION IN THE HEALTH CARE FIELD.

Brand name manufacturers have historically directed an exhaustive advertising campaign to health care professionals during the term of their patent monopoly on a drug product. They may deemphasize the generic name, or as in the present case, fail to even provide a useful generic name. As a consequence, many physicians come to identify a drug itself by the claimed "brand name" and write prescriptions accordingly.

---

[4] The District Court acknowledged that use of accustomed appearance "will facilitate generic substitution" and make the generic drug "more saleable because it makes it easier for both the doctor and pharmacist to substitute the generic drug" and that "the patient may resist such substitution" if it has an unaccustomed appearance [Petition Appendix, p. 9]. However, the District Court nevertheless based its grant of a monopoly on accustomed drug dosage form appearance by "predicat[ing] a rule of law upon an assumption that some pharmacists do and may illegally substitute generic drugs in order to make a greater profit" [Petition Appendix, p. 32]. This Court rejected in the *Inwood* case, *supra*, the "assumption that a pharmacist . . . will be unable to resist the temptation to profit from illegal activity" *Id.* 456 U.S. 844 at 856.

Congress had addressed the problem of failure to provide useful generic drug names in both the Trademark, and the Food, Drug and Cosmetic laws. Title 15 U.S.C. §1064(c) of the Lanham Trademark Act provides for cancellation of claimed trademarks which are "the common descriptive name of an article or substance", and Title 15 U.S.C. §1065(4) of the Lanham Act prevents acquisition of trademark rights in "the common descriptive name of any article or substance, patented or otherwise". In order to curb drug company failure to provide and promote useful generic drug names, and to "prevent profit when generic names cannot be remembered" [Congressional Record, Def. Ex. 31, Trial Record, pp. 952, 965, 982, 987-990], in 1962, Congress required that all prescription drug advertisements have a generic name printed in type at least half as large as that used for the claimed brand name 21 U.S.C. §352(n). Despite this requirement, none of Ciba's advertising relied on by the lower courts provides a useful generic name other than "Apresazide"; even the ingredient names are up to 20 or more times smaller than the claimed brand name "Apresazide" [Pl. Ex. 8-14, 19, Trial Record, pp. 1474-1548].

The legislatures of 49 states (including Illinois) have also sought to address the problem by adopting so-called "generic drug substitution laws" which either require or allow the dispensing pharmacist to dispense a generic drug when a "brand name" is written on the prescription, unless the physician otherwise directs.

The United States Adopted Names (USAN) Council, in cooperation with the official United States Pharmacopea, National Formulary, and the Food and Drug Administration, seeks to promote the selection and utilization of nonproprietary names for drugs:

> Teaching in pharmacy and medicine requires a common designation especially for a drug that is available from several sources, *and for combinations of two or more drugs.* Nonproprietary names greatly facilitate communication between physicians, and most journals demand their use. State formularies and hospital formularies generally use nonproprietary names as the titles of the articles recognized. A nonproprietary name is essential to the pharmaceutical manufacturer as a means of preserving his trademark rights in his brand name for the article concerned. Finally, federal law obliges the manufacturer to use the "established" nonproprietary name in his advertising, labels and brochures. [USAN and the USP Dictionary of Drug Names. USAN 1982, 1961-1981 Cumulative List, page 6; Dx. 24, Trial Record, p. 809] (emphasis supplied)

Despite this, Ciba-Geigy has provided no useful generic name for the drug in suit, other than its claimed brand name "Apresazide". Dr. O'Donnell correctly testified that a tongue-twisting listing of its ingredients—"Hydralazine Hydrochloride and Hydrochlorothiazide" is too cumbersome for use [Trial Record, pp. 353-361]. Patients certainly cannot remember these names. What name is to be used on prescription labels, and in patient communications? Ciba-Geigy's counsel acknowledged during his deposition of Dr. O'Donnell that he used "generic Apresazide because its easier than the mouthful describing the component parts" [April 21, 1982, Deposition of Dr. O'Donnell, p. 28, attached as Appendix pp. 1-2]. Ciba's own witnesses acknowledged that "Apresazide" is the common name for the drug and that physicians commonly refer to it as "Apresazide" [Trial Record, pp. 73-77, 136, 143, 147].

The Third Circuit decision frustrates the pharmaceutical and legal requirements for providing useful generic names.

Any association of drug product appearance with the name "Apresazide", where there is no other useful generic name, is an improper basis for the grant of a drug appearance monopoly. The trademark laws should not reward advertising, which fails to provide and promote a useful generic name, with a monopoly on the functional appearance characteristics of a drug dosage form.

CONCLUSION

For these reasons, the Illinois Pharmacists Association respectfully urges the Court to grant Certiorari to review the Third Circuit decision.

Respectfully submitted,

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APPENDIX

IN THE
UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

vs.

BOLAR PHARMACEUTICAL COMPANY, INC.,

Defendant.

Civil Action No. 82-0788 (HLS)

[1] The deposition of JAMES THOMAS O'DONNELL called by the Plaintiff for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before CATHERINE M. MROZEK, a Notary Public within and for the County of Cook, State of Illinois, and a Certified Shorthand Reporter of said state, at 1725 West Harrison Street, Chicago, Illinois, on the 21st day of April, A.D. 1982, at 2:00 p.m.

[2] PRESENT:

MESSRS. KAYE, SCHOLER, FIERMAN, HAYS & HANDLER,
(425 Park Avenue
New York, New York 10022), by:
MR. IRA SACKS,
appeared on behalf of the plaintiff;

MESSRS. FITCH, EVEN, TABIN, FLANNERY & WELSH,
(135 South LaSalle Street
Chicago, Illinois 60603), by:
MR. JOHN F. FLANNERY,
appeared on behalf of the Defendant.

REPORTED BY: CATHERINE M. MROZEK, C.S.R.

* * * * *

[27] Q. Are you aware of generic—and I'm saying generic Apresazide because it's easier than the [28] mouthful describing the component parts—of their plans to market a generic Apresazide?

A. Their meaning who, Reid-Provident?

Q. Reid-Provident.

A. No, I was not aware of that.

Q. Has anybody from Bolar made you aware that Reid-Provident intends to market a generic Apresazide in a green capsule?

MR. FLANNERY: No, that's assuming a fact not in evidence, Counsel.

MR. SACKS: Well, I'll be able to get that into evidence at the hearing.

* * * * *

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No. 83-1163

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OCTOBER TERM, 1983

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VS.

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Respondent.

BRIEF OF THE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS AS AMICUS CURIAE IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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The National Association of Pharmaceutical Manufacturers, Inc., ("NAPM") respectfully submits this brief as amicus curiae in support of the petition for a writ of certiorari by Bolar Pharmaceutical Co., Inc. ("Bolar") in the above-entitled matter. Pursuant to Supreme Court Rule 36.1, NAPM has obtained written consent for the filing of its amicus brief from the respective parties to the instant petition. A copy of said consent is annexed hereto at Addendum 1.

QUESTIONS PRESENTED

NAPM concurs in the questions presented in Bolar's petition for a writ of certiorari.

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Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc., 194 U.S.P.Q. 157 (D.N.J. 1977), *aff'd on procedural grounds*, 579 F.2d 786 (3d Cir. 1978) 2

Joseph Schlitz Brewing Co. v. Houston Ice & Brewing Co., 250 U.S. 28 (1919) 9

Sears Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964) 7, 9

SK&F Co. v. Premo Pharmaceutical Laboratories, Inc., 481 F.Supp. 1184 (D.N.J. 1979), *aff'd*, 625 F.2d 1055 (3d Cir. 1980) 2

SK&F Co. v. Premo Pharmaceutical Laboratories, 625 F.2d 1055 (3d Cir. 1980) ..... *passim*

Sony Corporation of America v. Universal City Studios, No. 81-1687, 52 U.S.L.W. 4090 (Jan. 17, 1984) 6-8

STATUTES CITED

Lanham Act, 15 U.S.C. §1051 *et seq.* 5, 6

OTHER AUTHORITIES CITED:

R.H. Stern, "The Persantine, Librax and Elavil Decisions: Colourful Brands of Drugs," 2 EUR. INTEL. PROP. REV. 59 (1981) 12-13

INTEREST OF THE AMICUS CURIAE

NAPM is a national trade association representing more than 100 manufacturers and distributors of prescription and "over-the-counter" pharmaceutical products.[1] For many years, NAPM has been the leading spokesperson for what is commonly known as the generic drug industry. NAPM has represented the industry in the courts (both as a party and as amicus), before administrative tribunals and in hearings before Congress and the legislatures of numerous states. NAPM previously participated as an amicus below before the Court of Appeals for the Third Circuit in the instant case and has been amicus curiae before this Court regarding the issues presented for review herein. *See InwoodLaboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982) (hereinafter "*Ives*").

THE SIGNIFICANCE OF THE ISSUES PRESENTED

It is respectfully submitted that the questions presented to this Court are not limited to the particular drug at issue. Rather, this Court's decision will have a significant and far-reaching impact on the entire drug industry and the manner in which drugs are prescribed to and used by the American public. The decision sought to be reviewed herein undermines the rule of law established by a unanimous Court in *Ives* and squarely presents the issue as to the appropriate standard for contributory liability under the Lanham Act, 15 U.S.C. §1051 *et seq.*, which Justice White raised in his concurring opinion in *Ives*.

Traditionally, generic drug products have been marketed in the same color as their well-known brand name counterparts. In recent years, however, brand name companies have undertaken a vigorous litigation effort to halt this long-standing practice. In a series of cases decided by the Court of Appeals for the Third Circuit and the District Court for the District of New Jersey,[2] the brand name companies were successful in advancing their revisionist view of the role of color in prescription

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[1]Petitioner Bolar is not a member of NAPM.

[2]*See American Home Products Corp. v. Chelsea Laboratories*, F.Supp. , Civ. Action No. 81-3351 (VPB) (D.N.J. Aug. 5, 1982), *aff'd without opinion*, F.2d. , No. , (3d Cir., Sept. 29, 1983); *Biocraft* (cont.)

pharmaceuticals. In an essentially contemporaneous case arising out of the District Court for the Eastern District of New York, a comprehensive decision affirmed the traditional view – a finding which was ultimately sustained by this Court. *Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 488 F.Supp. 394 (E.D.N.Y. 1980), *rev'd*, 638 F.2d 538 (2d Cir. 1981), *rev'd sub nom., Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), *aff'd sub nom. on remand, Ives Laboratories, Inc. v. Darby Drug Co., Inc.*, 697 F.2d 291 (2d Cir. 1982) (opinion not published per Second Circuit Rule 0.23).

As the instant case shows, the Third Circuit and the District of New Jersey nevertheless continue to grant monopoly color rights to brand name companies. NAPM submits this brief since, as this Court recognized in *Ives*, it is legally and scientifically indisputable that color plays a vital role in patient acceptance and utilization of prescription drugs. *See Ives*, 456 U.S. at 852, n.20 and 456 U.S. at 862-863 and n.3 (White, J., concurring). The decision below totally misconstrues the legal effect of the decision in *Ives* by disregarding this Court's complete rejection of the "reasonably anticipate" standard as a basis for contributory liability under the Lanham Act and its recognition of similarity of capsule color as a legitimate competitive use. The public interest requires that this Court reverse the decision of the Third Circuit to insure that patients for whom lower-cost generic products are prescribed are not subjected to the penalty of confusion, anxiety, mistake and potential injury

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(cont.)

Laboratories, Inc. v. Merck & Co., 532 F. Supp. 1068 (D.N.J. 1980); *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories*, 532 F.Supp. 1040 (D.N.J. 1980); *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 481 F.Supp. 1184 (D.N.J. 1979), *aff'd*, 625 F.2d 1055 (3d Cir. 1980); *Hoffman LaRoche v. Premo Pharmaceutical Laboratories, Inc., 210 U.S.P.Q. 374 (D.N.J. 1980); Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977), *aff'd on procedural grounds*, 579 F.2d 786 (3d Cir. 1978). Additionally, numerous other cases have been filed in the District of New Jersey by virtually every brand-name company in order to enjoin the marketing of generic drug products in colors which are similar to their brand-name counterparts. *See e.g., Sandoz, Inc. v. Danbury Pharmacal, Inc.*, 83 Civ. 4771 (D.N.J.) (complaint filed Dec. 12, 1983); *Ciba-Geigy Corp. v. Zenith Laboratories, Inc., et al.*, 82 Civ. 671 (D.N.J.) (complaint filed March 4, 1982).

resulting from a judicially imposed requirement of color differentiation between generic and brand name drugs.

REASONS FOR GRANTING THE WRIT

I.

A WRIT OF CERTIORARI SHOULD ISSUE TO REJECT THE LOWER COURT'S DEVIATION FROM THE STANDARD OF CONTRIBUTORY LIABILITY SET FORTH BY THIS COURT IN IVES

The Third Circuit and the District of New Jersey applied a standard of contributory liability which was expressly rejected by this Court. Under the standard applied, Bolar was enjoined from manufacturing a generic drug product in the same color as its brand-name counterpart, under the theory that it could "reasonably anticipate" that some pharmacists might unlawfully substitute its product for Ciba-Geigy's or commit other acts of so-called unfair competition. The supposed rationale for such liability is that color similarity between generic and brand-name drugs makes it easier for such illegal acts to occur.

In *Ives*, however, the test for determining contributory liability was reaffirmed as follows:

> As the lower courts correctly discerned, liability for trademark infringement can extend beyond those who actually mislabel goods with the mark of another. Even if a manufacturer does not directly control others in the chain of distribution, it can be held responsible for their infringing activities under certain circumstances. Thus, if a manufacturer or distributor *intentionally induces* another to infringe a trademark, or if it *continues to supply its product to one whom it knows or has reason to know* is engaging in trademark infringement, the manufacturer or distributor is contributorially responsible for any harm done as a result of the deceit. See *William R. Warner & Co., v. Eli Lilly & Co.*, supra; *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, supra.

Ives, 456 U.S. at 853-854 (footnote omitted) (emphasis added).

In contrast to the "intent" requirement for contributory liability as established by *Ives*, the so-called "reasonably anticipate" standard holds a manufacturer *per se* contributorily liable merely because it may anticipate that some unknown number of pharmacists, to an unknown extent, might illegally substitute the generic prescription drug product for its brand name prescription equivalent, or commit certain other unspecified unfair competitive acts, and that color similarity might facilitate such acts.

Prior to *Ives*, the "reasonable anticipation" standard was utilized by the Third Circuit to find contributory liability by a generic drug manufacturer. *SK&F Co. v. Premo Pharmaceutical Laboratories*, 625 F.2d 1055, 1065-66 (3d Cir. 1980) (hereinafter "*SK&F*"). Subsequent to *Ives*, the Third Circuit has continued to apply the "reasonably anticipate" standard to support a finding of contributory liability despite this Court's express rejection of it. In *Ives*, this Court observed:

> Justice White's concern [that we may have silently acquiesced in a change in the test for contributory infringement] is based on a comment by the Court of Appeals that the generic manufacturers 'could reasonably anticipate' illegal substitution of their drugs, 638 F.2d at 543. *If the Court of Appeals had relied upon that statement to define the controlling legal standard, the court indeed would have applied a 'watered down' and incorrect standard.* As we read the Court of Appeals' opinion, however, that statement was intended merely to buttress the court's conclusion that the legal test for contributory infringement, as earlier defined, had been met.[3]

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[3]The majority's decision thus comports with Justic White's statement that:

> [t]he mere fact that a generic drug company can anticipate that some illegal substitution will occur to some unspecified extent, and by some unknown pharmacists, should not by itself be a predicate for contributory liability.

Ives, 456 U.S. at 861 (White, J., concurring).

Ives, 456 U.S. at 854, n.13 (emphasis added).

In affirming the District of New Jersey's determination of contributory liability by Bolar, the Third Circuit attempted to distinguish *Ives* on the theory that the lower court's finding of Bolar's contributory liability could be premised upon state rather than federal law. The Court of Appeals thus stated it was not necessary to reach the question of whether *Ives* overruled *SK&F's* "reasonably anticipate" standard for contributory liability since:

> [t]he district court's conclusions regarding the New Jersey state law claims of 'passing off' and 'unprivileged imitation' are mandated by *SK&F's* and provide a sufficient independent basis for affirming the district court's grant of preliminary injunctive relief.

Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc., 719 F.2d 56, 57 n.1 (3d Cir. 1983)

In the first instance, the Third Circuit's reliance on *SK&F* raises the exact issue about which Justice White had expressed concern in *Ives*. More significantly, the Third Circuit's purported distinction between state unfair competition law and federal trademark law with respect to the appropriate standard for contributory liability is erroneous.

An examination of the *SK&F* decision reveals that its finding that the generic manufacturer was contributorily liable for the New Jersey state tort of "passing off" was founded upon the "reasonably anticipate" standard. Indeed, the Third Circuit in *SK&F* stated:

> Moreover, it has been held that it is actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form in which the manufacturer can *reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off*. (citations omitted).

SK&F, 625 F.2d at 1062 (emphasis added).

Further, in concluding that *SK&F*'s showing that it was likely to succeed on its unfair competition claim under state law would therefore also support a finding of success under §43(a) of the Lanham Act, the *SK&F* court observed:

> Since, except for the interstate commerce requirement, the elements of the unfair competition torts proscribed by New Jersey law and by Section 43(a) of the Lanham Act *are the same*, we need not repeat the factual discussion as to likelihood of success on the merits of the federal cause of action.

Id. at 1066 (emphasis added).

Thus, it is clear that the "reasonably anticipate" standard which was applied in the instant case by the District Court and affirmed by the Third Circuit Court of Appeals to find contributory liability by Bolar, is the *same* standard which was used to find contributory liability in *SK&F* under the unfair competition law of the State of New Jersey, as well as the Lanham Act. *Compare SK&F*, 625 F.2d at 1062 with *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc.*, 547 F.Supp. 1095, 1115-1116 (D.N.J. 1982). It is this standard which was explicitly repudiated by the Court in *Ives*.

The *Ives* Court adopted the far different articulation of contributory liability set forth in *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, 64 F.Supp. 980 (D. Mass. 1946), *aff'd*, 162 F.2d 280 (1st Cir.) *cert. denied*, 332 U.S. 809 (1947). In *Snow Crest*, a single standard of contributory liability was established for both state unfair competition and federal trademark infringement. Therefore, the test for contributory liability for unfair competition under state law cannot be greater than the "intent" standard enunciated by this Court in trademark cases; a test which this Court recently characterized as "narrow". *Sony Corporation of America v. Universal City Studios*, No. 81-1687, 52 U.S.L.W. 4090, 4094, n.17 (Jan. 17, 1984). Otherwise, this Court's narrow interpretation of contributory liability would

be rendered meaningless since every action could be styled as one in state unfair competition rather than trademark infringement.

The Third Circuit's use of the reasonably anticipate standard also creates additional confusion as to the appropriate measure for contributory liability. Justice White observed that this confusion might exist unless the question presented to this court was resolved. *Ives*, 456 U.S. at 619-620 (White, J., concurring). The Third Circuit's resort to state law in order to distinguish *Ives* binds generic manufacturers to a standard of liability that is unsupported by case law. Moreover, the court's remedy – an injunction against the copying of a functional unpatented, trademarked, or copyrighted feature – violates this Court's express holding in *Sears Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964).

It is respectfully submitted that a writ of certiorari issue to reverse the Third Circuit's error in continuing to insist on applying a standard of contributory liability which is impermissible and in contravention of this Court's opinion in *Ives*.[4]

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[4]Alternatively, the Third Circuit affirmed the District Court finding that Bolar had intended to facilitate illegal substitution by its manufacture of generic drugs which utilized the same capsule colors as the brand-name product and was therefore liable even under this Court's standard for contributory passing off. No evidence of such an intent was identified by either the District Court or the Third Circuit other than the fact that the same color was used. Once again, this Court in *Ives* directly addressed and rejected this type of analysis:

> The Court of Appeals cited no evidence to support its conclusion, which apparently rests upon the assumption that a pharmacist who has been provided an imitative generic drug will be unable to resist the temptation to profit from illegal activity. We find no support in the record for such a far-reaching conclusion.

Ives, 456 U.S. at 856, n.17. The District Court's discussion of Bolar's alleged intent is irrelevant to the criteria which must be examined to find contributory liability under the *Ives* test. The *Ives* standard requires a showing that a drug (cont.)

II.
A WRIT OF CERTIORARI SHOULD ISSUE TO REAFFIRM THIS COURT'S FINDING THAT COPYING OF DRUG CAPSULE COLOR DOES NOT CONSTITUTE COPYING OF A "NON-FUNCTIONAL" FEATURE

The Third Circuit also affirmed the District's Court finding that Bolar's mere copying of capsule color, *a fortiori* caused it to be liable for the so-called tort of "unprivileged imitation" under New Jersey state law and supported a ban against color copying for prescription drugs.[5] *But cf., Sony Corporation v. Universal City Studios*, 52 U.S.L.W. at 4095, n.19.

The finding of "unprivileged imitation" was premised upon the erroneous conclusion of non-functionality for capsule color. Bolar, in good faith, was surely entitled to rely on the overwhelming body of scientific information which demonstrates functionality of color, as recognized by this Court in *Ives* [6], even if the Third Circuit and the District Court of New Jersey were not persuaded thereby.

(cont.)

manufacturer intentionally *induced* another to commit unfair trade practices by reason of some act other than the manufacture of a pharmaceutical product in the same color. Moreover, after this Court's recent decision in *Sony Corporation of America v. Universal City Studios, supra*, it is beyond peradventure that the mere fact that a generic drug product looks like its brand-name equivalent cannot serve as the basis for a finding of contributory liability under federal or state law. This Court's restatement of the *Ives* standard in *Sony* underscores the rule of law that color alone is not enough to constitute a violation of trademark law or unfair competition under the theory of contributory liability. See *Sony*, 52 U.S.L.W. at 4095 n.19

[5]As applied by the District Court in the instant case and affirmed by the Third Circuit, the elements of the tort of unprivileged imitation under state law are generally expressed as conjunctive requirements of non-functionality and secondary meaning. *Ciba-Geigy v. Bolar*, 547 F.Supp. at 1110.

[6]In *Ives*, this Court pointed out: "By establishing to the District Court's satisfaction that uniform capsule colors served a functional purpose, the petitioners offered a legitimate reason for producing an imitative product." 456 U.S. at 857 at n.20. This Court characterized the evidence which satisfied the *Ives* District Court as follows:

> In reaching its conclusion, the court found that the ... colors were functional to patients as well as to doctors and hospitals: many elderly patients associate color with therapeutic effect; some patients commingle medications in a container and rely on color (cont.)

The essence of the analysis by the Third Circuit and the District Court of New Jersey with respect to "unprivileged imitation" appears to be that copying is a practice which should be condemned. This is a philosophical view of economics which contravenes almost one hundred years of controlling precedent. *See Coats v. Merrick Thread Co.*, 149 U.S. 562, 573-574 (1893); *A. Leschen & Sons Rope Co. v. Broderick & Bascom Rope Co.*, 201 U.S. 166, 171 (1906); *Jos. Schlitz Brewing Co. v. Houston Ice & Brewing Co.*, 250 U.S. 28, 29-30 (1919).

This Court, however, has reiterated that free and open competition necessarily requires that "imitation" be encouraged and that the right to copy, absent legitimate patent, trademark or copyright protection, cannot be constricted:

> Sharing in the goodwill of an article unprotected by patent or trademark is the exercise of a right possessed by all – and in the free exercise of which the consuming public is deeply interested.

Kellogg Co. v. National Biscuit Co., 305 U.S. 111, 122 (1938). *See also Sears Roebuck & Co. v. Stiffel Co.*, 376 U.S. at 230-233; *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. at 238.

Indeed, in *Sears/Compco* this Court recognized that the states were barred by the constitutional doctrine of preemption from prohibiting the type of copying presently enjoined by the Third Circuit under New Jersey law:

> That an article copied from an unpatented article could be made in some other way, that the design is 'nonfunctional' and not essential to the use of either

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(cont.)

> to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand-name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs.

456 U.S. at 853.

Justice White also noted that the finding of functionality was supported in several respects: "Patient anxiety and confusion were likely if accustomed medicine were dispensed in a different color; capsule colors assist patients in identifying the correct pill to take; standard colors help physicians identify the drug involved in case of overdose." 456 U.S. at 862 (White, J. concurring).

> article, that the configuration of the article copied may have a 'secondary meaning' which identifies the maker to the trade, or that there may be 'confusion' among purchasers as to which article is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling; however, and regardless of the copier's motives, *neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling.*

Compco, 376 U.S. at 238 (emphasis added).

The lower courts also seemed perturbed by the fact that Bolar (and other generic manufacturers) seek to derive a financial gain from the copying of capsule color. The profit motive, however, is the essence of competition in a free society and should be encouraged rather than denigrated. The functionality of capsule colors makes it imperative for generic companies to copy drug color because it is essential to fully effective competition.

It is most striking to contrast the opinion of the District Court of New Jersey in the instant case and the concurring opinion of Mr. Justice White concerning functionality of capsule color for medicines:

DISTRICT OF NEW JERSEY:

> Nor was there any medical, pharmaceutical or manufacturing reason which compelled Bolar to copy the dosage form or color combinations from Ciba-Geigy."

547 F.Supp at 1111.

> To suggest that the very same colors must be used is to defy common sense.

Id.

> It is inconceivable that a physician or a pharmacist would prescribe a drug based upon its appearance only. Such appearance may be utilized as a secondary

> or incidental means of identification, but such use hardly rises to the level of functionality which would mandate or permit copying.

Id.

MR. JUSTICE WHITE:

> 'The reality is that for every link in the distributive chain (from producer to ultimate consumer) the color and shape of drugs dispensed by prescription do perform a function. For each of them, color or shape may be a convenient shorthand code by which to identify the drug and its milligram dosage so that mistakes can be avoided in the interests of pharmaceutical precaution and patient safety. For the patient-user, of course, the constancy of color and shape may be as psychologically reassuring and there fore as medically beneficial as the drug itself; in addition, they also serve to identify the drug for its ingestion. . .
>
> *[I]f the generic producer is constrained by §43(a), trademark law, or the law of unfair competition to adopt a substantially different color. . . the therapeutic value of his generic drug might be seriously impaired and confusion at the pharmacist level could be compounded beyond redemption.* 3 R. Callmann, Unfair Competition, Trademarks and Monopolies §82.1(m), pp. 217, 213 (Supp. 1981).'

Ives, 456 U.S. 862, n.3 (White, J., concurring) (emphasis added).

> A functional characteristic is 'an important ingredient in the commercial success of the product,' 601 F.2d at 643, and, after expiration of a patent, it is no more the property of the originator than the product itself. It makes no more sense to base contributory infringement upon the copying of functional colors than on the petitioners' decision to use the same formulation of the drug, or even to market the generic substitute in the first place. To be sure, the very existence of

> generic drugs 'facilitates' illegal substitution, but Ives no longer has a patent for cyclandelate, 'and the defendants have a right to reproduce it as nearly as they can.' *Saxlehner v. Wagner*, 216 U.S. 375, 380, 54 L.Ed. 525, 30 S.Ct. 298 (1910) (Holmes, J.). Reproduction of a functional attribute is legitimate competitive activity.

Id., at 863 (White, J., concurring).

If the Third Circuit's reasoning was correct, Coca-Cola should be entitled to a monopoly on its brown colored soda under either the so-called state law tort of unprivileged imitation or passing off because (a) the brown color is unnecessary or non-functional for manufacturing purposes since any color can be added to soda and still allow it to taste like cola; (b) the companies who entered the cola market after Coca-Cola are copying Coke's brown color for their own use and thereby deriving an economic benefit, and (c) the potential of illegal color substitution of other Cola drinks for Coca-Cola is great and could be reasonably anticipated by these newer manufacturers.[7] However, until Congress determines that the trademark or patent laws need to be amended to allow companies such as Coca-Cola and Ciba-Geigy to maintain monopolies over color, the refusal to permit such relief as established in *Coca-Cola v. The Koke Company of America*, 254 U.S. 143 (1920); *Coca-Cola Co. v. Snow Crest Beverages*, *supra*, and *Ives* must stand.

NAPM respectfully urges that this Court reverse the absolute protectionist view taken by the Third Circuit and the District of New Jersey.[8]

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[7]Surely, the potential for illegal acts is not greater among pharmicists than among bartenders and restaurateurs, who were found to have no such propensity in *Snow Crest*.

[8]One legal commentator's observation before *Ives* about the decisions rendered by the Third Circuit and the District of New Jersey on the questions presented to this Court appears to still be applicable:

> Perhaps one's expectations must necessarily be limited, but the level of analysis in the recent colour get-up judgments has fallen (cont.)

CONCLUSION

It is respectfully submitted that a writ of certiorari be issued to the United State Court of Appeals for the Third Circuit as prayed for.

Respectfully submitted,

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(cont.)

extraordinarily low. The courts seem to be indulging in non-sequiturs, fits of pique, and bizarre overreactions, instead of making measured, rational, dispassionate responses to whatever problems there are in resolving these business conflicts. Moreover, the distribution of what seems to be error and mistake is now quite unrandom; there had been a definite tilt in favour of the brand name drug companies, against the generic sellers. One would not think this to be one of the great political issues of the times; that distorts perception and judicial impartiality. Yet the courts seem to be reacting to generic sellers as if they were trying to subvert Government. Why the courts are doing so seems inexplicable in terms of ordinary common law legal analysis methods based on the categories of trade mark and unfair competition law as they have been developed in regard to other products. Something may be going on in these cases that is not reflected in lines of the courts' published opinions. To predict these judgments is now simple, for the same side always wins. To understand the judgments, perhaps, use of a different discipline is required.

See R.H. Stern, "The Persantine, Librax & Elavil Decisions: Colourful Brands of Drugs", 2 EUR. INTEL. PROP. REV. 59 (1981).

ADDENDUM

No. 83-1163

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

CIBA-GEIGY CORPORATION,

Respondent.

CONSENT TO FILE BRIEF OF AMICUS CURIAE

Pursuant to the Rules of the Supreme Court of the United States, Rule 36.1, the undersigned counsel for the parties in the above-captioned matter hereby consent to the filing of a brief by the National Association of Pharmaceutical Manufacturers as Amicus Curiae in support of the Petition for a Writ of Certiorari.

Dated: January 27, 1984

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No. 83-1163

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

BOLAR PHARMACEUTICAL CO.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

On A Petition For A Writ of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF *AMICUS CURIAE* THE NATIONAL COUNCIL OF SENIOR CITIZENS

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BOLAR PHARMACEUTICAL CO.,

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On A Petition For A Writ of Certiorari To The United States Court Of Appeals For The Third Circuit

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BRIEF OF *AMICUS CURIAE* THE NATIONAL COUNCIL OF SENIOR CITIZENS

INTEREST OF THE NATIONAL COUNCIL OF SENIOR CITIZENS

The National Council of Senior Citizens (NCSC) of 925 15th Street, N.W., Washington, D.C. 20002, pursuant to Rule 36.1 of the Rules of the United States Supreme Court, files the attached brief Amicus Curiae on a Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

The National Council of Senior Citizens ("NCSC") is a not-for-profit membership organization of over four thousand affiliated local associations having a membership of over four million senior citizens.

The National Council of Senior Citizens advocates the interests of senior citizens concerning governmental regulations, legislation and judicial decisions in areas of health care that affect the elderly, particularly including decisions which will adversely affect the health care interests of senior citizens.

The National Council of Senior Citizens was initially formed as an advocate for proper health care for the elderly; it fought for enactment of the legislation establishing the Medicare program, and has vigorously opposed efforts to dilute that program. Recognizing that retired persons and other senior citizens cannot expect medical care superior to or more cost-effective than that which is available to all of the population, the four million plus senior citizens it represents are vitally interested in the quality and the cost of health care programs for all Americans.

One aspect of medical care that places a particularly heavy burden upon the elderly is the cost of medication. This cost is not adequately covered by Medicare or by the most widely used Medicare supplemental health insurance policies. Moreover, the cost of medication has been increasing more rapidly than cost of living increases in Social Security, upon which many elderly persons rely as a principal source of income.

It has been estimated that the elderly spend nearly 20 times more on pharmaceutical expenses, as a percentage of income, than the rest of the population. The National Council of Senior Citizens has both anecdotal and statistical evidence that the high cost of drugs is a burden upon the elderly, which may in some cases even prevent senior citizens from following drug regimens prescribed for them. Often such drug regimens control symptoms or

manage diseases so as to prevent more costly medical treatment.

The decision of the Third Circuit in this case adversely affects the rights of senior citizens to purchase medication from competitive sources in the accustomed appearance which they use to recognize and identify their drugs. The elderly do not want to be forced to pay for exorbitant and unnecessary "detailing" and advertising costs and profits to a former patent monopolist, long after a patent has expired on a drug they need in recognizable form to maintain their health. The Third Circuit decision artificially establishes one monopoly source for formerly patented drugs in their accustomed form.

NCSC has considerable anecdotal evidence from its members of the hardships which artificially supported drug prices can impose upon them. NCSC, and the other major membership organizations of the elderly, provide pharmacy services at discount prices for their members and rely on the competition provided by generic drug manufacturers to reduce drug costs.

Appearance is important to medicine users. Many of the elderly follow their regimen by color codes—the "blue pill" and the "green pill" in the morning, and the "orange pill" at bedtime, etc. This habit is strong among many users, but is particularly strong among the elderly. The lower court decision will block the availability of reasonably priced generic drugs to NCSC members, to others of the elderly population, and to all citizens.

Not only does the lower court decision grant a monopoly on the very appearance by which senior citizens use to recognize and identify their medication, but it also grants a monopoly on the *only useful* name provided by the former patent monopolist for the drug.

For these reasons, the NCSC believes that the intent of Congress and of the generic drug substitution laws of the various States is being circumvented, and the health of its members and other senior citizens is being endangered, by the lower court decisions.

ARGUMENT

I. The Lower Court Decisions Impede Competition By Granting A Perpetual Monopoly On The Reproduction Of A Feature Which Contributes Directly To The Sale Of The Underlying Product

Consumers, particularly senior citizens, recognize and identify their drugs by the accustomed appearance of the drugs. When drug patents expire, senior citizens should be entitled to have competitors manufacture drugs in the accustomed dosage form of the drug. This right was clearly established by this Court in *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111 (1938) at page 120:

> Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights *in a form in which the public has become accustomed to see the article* and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind. [emphasis supplied]

In its recent decision in *Inwood Laboratories, Inc. et al.*, v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982), this Court properly recognized the utility of drug appearance for drug identification, health and safety purposes unrelated to any trademark purpose, in affirming the District Court decision:

> . . . that the blue and blue-red colors were functional to patients as well as to doctors and hospitals: many elderly patients associate color with therapeu-

> tic effect; some patients co-mingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs. [456 U.S. at 853.]

The NCSC fully supports these factors of drug appearance utility approved by this Court in the *Inwood* case. These factors have been improperly disregarded by the lower courts in the Petitioner's case. The outcome of these cases should not depend on which side of the Hudson River a "brand name" drug company decides to sue a generic drug manufacturer. The NCSC respectfully urges the Court to establish, throughout the United States, that the appearance of a drug product, which is the means consumers have had to recognize and identify the drug during the term of a patent monopoly, cannot continue to be monopolized under the trademark laws after expiration of a patent.

II. The District Court Decision Grants A Monopoly On The Only Useful Name For A Prescription Drug

The District Court, in order to support its injunction, held that "Hydralazine Hydrochloride and Hydrochlorothiazide" is the generic name for the drug in suit. However, the only useful name known by consumers is "Apresazide", the claimed brand name.

None of the Ciba-Geigy's advertisments promoting "Apresazide" shows a useful generic name. Contrary to the court decision, a complicated list of ingredients—"Hydralazine Hydrochloride and Hydrochlorothiazide"—is not a useful generic name for senior citizens, or other persons, to remember and use as the name of their drug.

This decision conflicts with the policies of the Trademark laws and Food, Drug and Cosmetic laws by granting respondent a monopoly on the only useful name for a prescription drug. When enacting the trademark laws, Congress required that a name which is or becomes the "common descriptive name" of a drug not be monopolized as a trademark. 15 U.S.C. §§ 1064(c), 1065(4). Later, in 1962, because of drug companies' failures to list the generic name, or because of listing it in type too small a size, and because of abuses such as the spectacle of a large manufacturer of drugs failing to designate any generic name at all, Congress enacted 21 U.S.C. § 352(n) to require all prescription drug promotion to have a generic name printed in type at least half as large as that used for the claimed tradename.[1]

Accordingly, it is the policy of the Trademark laws and the 1962 Amendments to the Food, Drug and Cosmetic laws to require "brand name" drug companies to provide and promote a generic drug name which can be remembered and used easily by persons who do not have a degree in pharmaceutical chemistry. The only useful name provided by Ciba-Geigy for senior citizens and other consumers is "Apresazide," which must necessarily be used as "the name for a drug in whose curative properties they had got confidence" *Bayer Co., Inc.* v. *United Drug Co.*, 272 F. 505, 510 (S.D.N.Y. 1921) (L.Hand). The decision of the lower courts frustrate the policy of these laws.

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[1] Respondent's advertising of its Singoserp, Nupercaine and Privine products was cited in Congress as examples of the practices which were to be prevented by the 1962 Amendments. Hearings before the Subcommittee on Antitrust and Monopoly of the Senate Committee on Judiciary, 87th Cong., 2nd Sess. (3374-3403) (1962) Trial R. at 982, 987-990.

III. The Lower Court Decision Interferes With State Law Policy Promoting Use Of Generic Drugs

The lower court decision also interferes with the policy of state generic drug substitution laws enacted by 49 states. Although the lower court acknowledges that the known appearance of a drug facilitates patient acceptance and generic substitution by doctors and pharmacists, which is the purpose of the state generic substitution laws, the decision nevertheless prohibits the manufacture and sale of such drugs.

That the judicial grant of a drug appearance monopoly interferes with the state substitution laws was argued by the New York Attorney General in his Amicus Brief in the *Inwood* case, and was acknowledged by Justice White in his concurring opinion in *Inwood Laboratories, Inc. et al.* v. *Ives Laboratories, Inc.*, 456 U.S. 844, 861 (1982):

> Preventing the use of generic drugs of the same color to which customers had become accustomed in their prior use of the brand name product interferes with the important state policy, expressed in New York and 47 other states, of promoting the substitution of generic formulations.

CONCLUSION

Amicus has a strong interest in encouraging competition within the pharmaceutical industry. Granting a perpetual monopoly on product appearance despite its functional character would seriously erode such competitive forces.

WHEREFORE, the National Council of Senior Citizens respectfully requests that this court grant the Petitioner's request for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

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